PROCEDURE MANUAL

OBJECTIVE 1

REDUCED FORMAT

TABLE OF CONTENTS

OVERVIEW **3**

FLOW CHART **4**

OBJECTIVE 1: STEPS FOR CONTACT **7**

MAIL / TELEPHONE CONTACTS & SCREENING MEASURES 9
APPENDIX A: CANDIDATE SELECTION AND REGISTRATION PROCEDURE 10
APPENDIX B: INTRODUCTORY LETTER TO PARENTS 12
APPENDIX C: BROCHURE 13
APPENDIX E: BRIEF TELEPHONE SCREENING INTERVIEW (4:6+) 15
APPENDIX H: DESCRIPTION OF STUDY 22
APPENDIX J: CBCL – CHILD BEHAVIOR CHECKLIST (1:6 – 18:0+) 23
APPENDIX P-1: FOLLOW-UP CBCL TELEPHONE CALL (CBCL SCORED, OK FOR STUDY) 24
APPENDIX Q: FULL TELEPHONE SCREENING INTERVIEW (4:6+) 25
APPENDIX R: DIAGNOSTIC INTERVIEW SCHEDULE FOR CHILDREN (C-DISC) TEST INSTRUCTIONS (7:0+) 35
APPENDIX S: DISC PREDICTIVE SCALES (DPS-4 INTERVIEW) - TEST INSTRUCTIONS FOR ADMINISTRATION (11:0+) 41
APPENDIX T: FIGS-MRI – FAMILY HISTORY INTERVIEW FOR GENETIC STUDIES – YEAR 1 (4:6+) 43

IN-HOUSE PROCEDURES (PARENT) **46**

(BRIEF) TEST DESCRIPTION: BEHAVIOR RATING INVENTORY OF EXECUTIVE FUNCTION (4:6+) 47
(JTCI) JUNIOR TEMPERAMENT AND CHARACTER INVENTORY TEST DESCRIPTION 48

IN-HOUSE PROCEDURES (CHILD/ADOLESCENT) **49**

PHYSICAL/NEUROLOGICAL EXAMINATION (4:6+) 50
TEST DESCRIPTION: PUBERTAL DEVELOPMENT SCALE (4:6+) 57
SALIVA SAMPLING: TEST DESCRIPTION 58
URINE SAMPLE: TEST DESCRIPTION 59
PREGNANCY TEST: TEST DESCRIPTION 60
MR PROCEDURES 61
MRI SAFETY CHECKLIST 62
MR TECHNOLOGIST'S FORM 64
HANDEDNESS (4:6 – 5:11) 65
(DAS) DIFFERENTIAL ABILITY SCALES (4:6 – 5:11) 70
WASI: WECHSLER ABBREVIATED SCALE OF INTELLIGENCE (6:0+) 73
WISC III – WECHSLER INTELLIGENCE SCALE FOR CHILDREN III: DIGIT SPAN & CODING (6:0 – 16:11) 78
WAIS - R: WECHSLER ADULT INTELLIGENCE SCALE – REVISED DIGIT SPAN & DIGIT SYMBOL (17:0+) 79
WOODCOCK-JOHNSON III: (4:6+) 80
VERBAL FLUENCY (NEPSY - SEMANTIC & PHONEMIC) (7:0+) 82
CVLT-C: CALIFORNIA VERBAL LEARNING TEST FOR CHILDREN (4:6 – 15:11) 84
CVLT-II: CALIFORNIA VERBAL LEARNING TEST, 2ND EDITION (16:0+) 85
CANTAB: (CAMBRIDGE NEUROPSYCHOLOGICAL TEST BATTERY) 86
PURDUE PEGBOARD 87
(JTCI) JUNIOR TEMPERAMENT AND CHARACTER INVENTORY: TEST DESCRIPTION **ERROR! BOOKMARK NOT DEFINED.**
QUALITY CONFIRMATION – BEHAVIORAL/NEUROBEHAVIORAL TESTS, INTERVIEWS, & NEUROLOGICAL EXAMS 89

EXCLUSIONARY CRITERIA **98**

GENERAL EXCLUSIONARY CRITERIA 99
APPENDIX AF: EXCLUSIONARY PRENATAL MEDICATIONS 103
APPENDIX AG: HEIGHT AND WEIGHT CHARTS 123

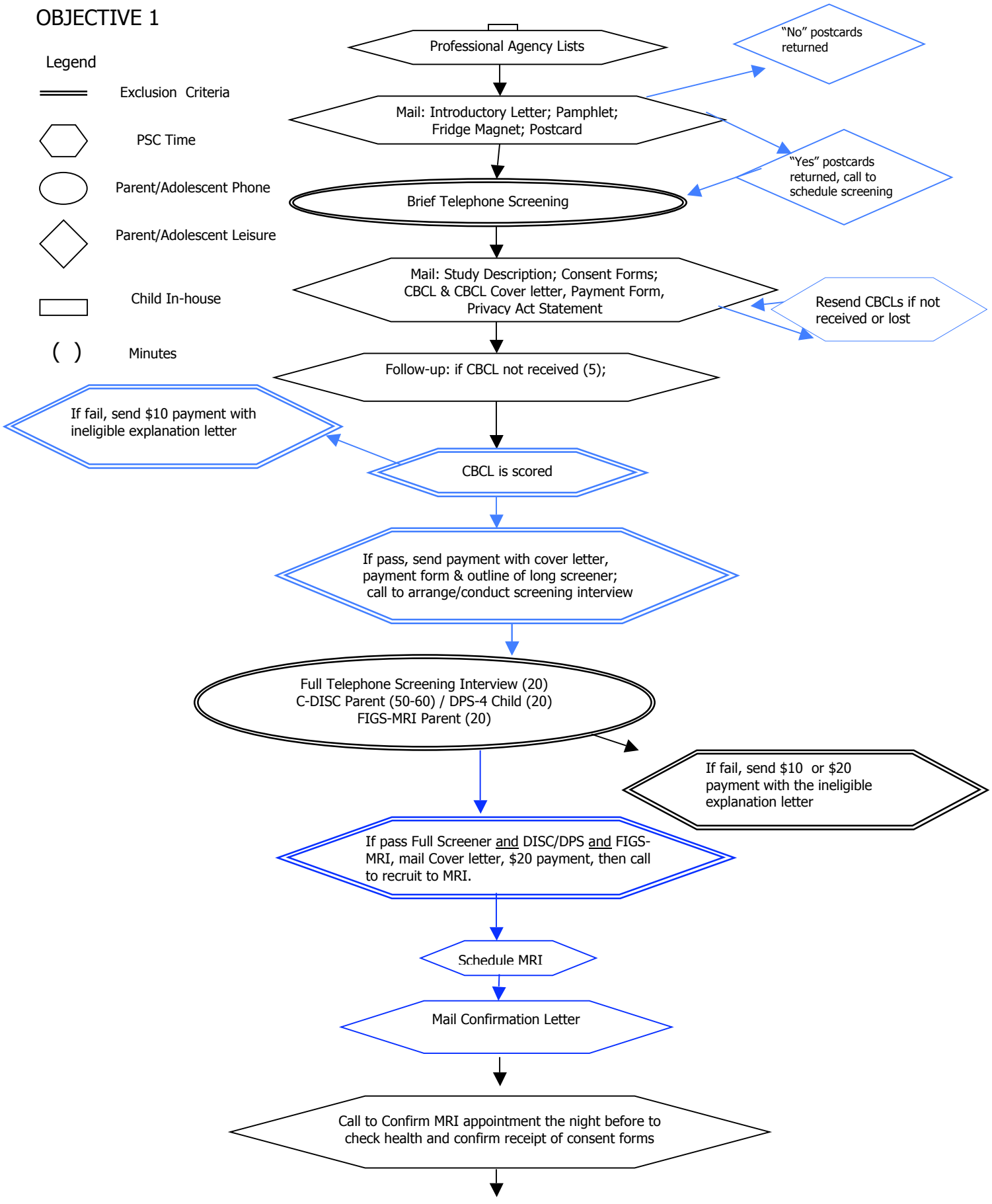
Overview

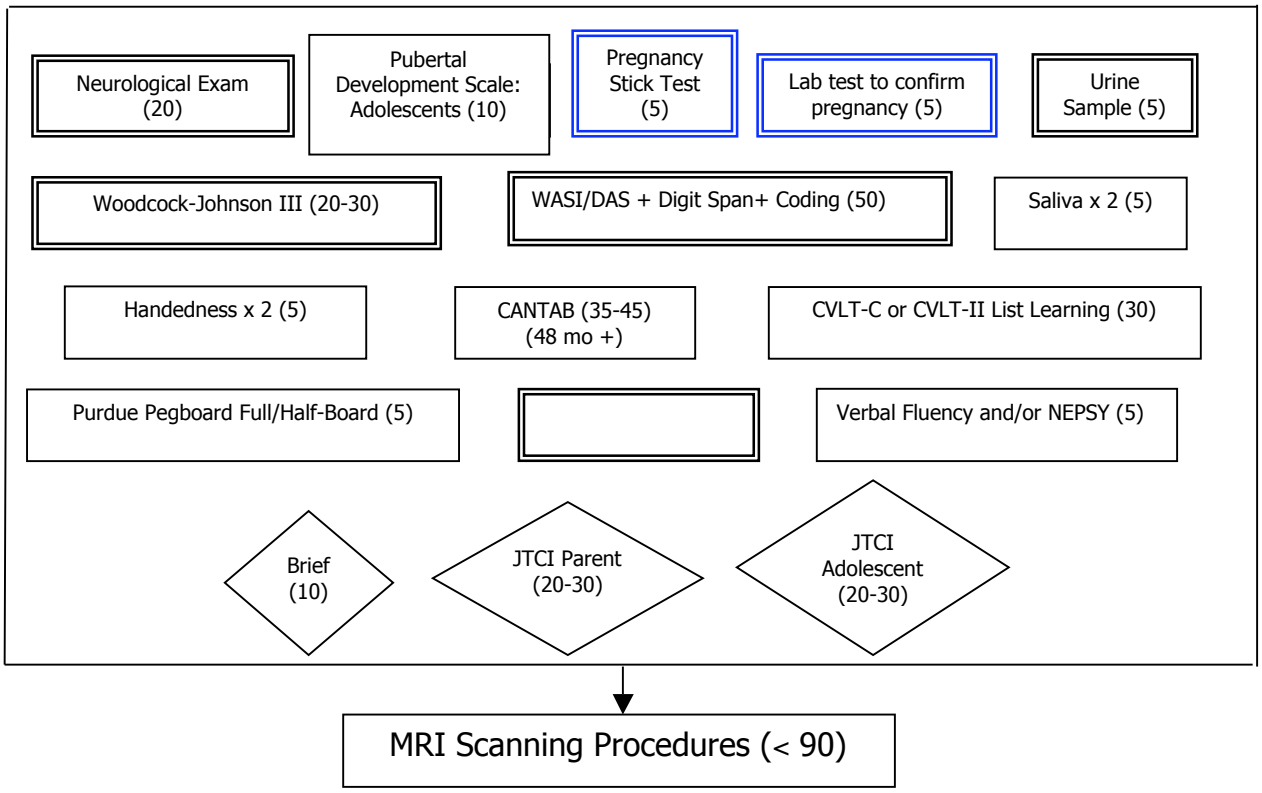
The main goal of the study is to provide a normative database of the developing human brain for comparison with MRI studies of children with neurological, developmental, and psychiatric disorders and also to provide longitudinal data for investigating brain maturation in relation to behavioral and cognitive development in a healthy sample.

The Visit One database is ready for its introduction to the research community. Interested investigators will be able to obtain full and partial data sets of clinical/behavioral and image data. This procedure manual details the procedures employed in the study involved with initial cuts, screening and in-house day of visit procedures. This is a markedly shortened version of the study Procedure Manual, some Appendices are not included, as they were not relevant to the public data release. Thus some Appendices labeling is not sequential, but retains the original Appendices labeling. Screening to behavioral instruments are provided or described and commercially available instruments are described in more general terms. Detailed instructions are available to investigators who purchase those instruments.

Flow Chart

OBJECTIVE 1


Legend
Exclusion Criteria
PSC Time
Parent/Adolescent Phone
Parent/Adolescent Leisure
Child In-house
( ) Minutes
Professional Agency Lists
"No" postcards returned
Mail: Introductory Letter; Pamphlet; Fridge Magnet; Postcard
"Yes" postcards returned, call to schedule screening
Brief Telephone Screening
Mail: Study Description; Consent Forms; CBCL & CBCL Cover letter, Payment Form, Privacy Act Statement
Resend CBCLs if not received or lost
Follow-up: if CBCL not received (5);
If fail, send $10 payment with ineligible explanation letter
CBCL is scored
If pass, send payment with cover letter, payment form & outline of long screener; call to arrange/conduct screening interview
Full Telephone Screening Interview (20)
C-DISC Parent (50-60) / DPS-4 Child (20)
FIGS-MRI Parent (20)
If fail, send $10 or $20 payment with the ineligible explanation letter
If pass Full Screener and DISC/DPS and FIGS-MRI, mail Cover letter, $20 payment, then call to recruit to MRI.
Schedule MRI
Mail Confirmation Letter
Call to Confirm MRI appointment the night before to check health and confirm receipt of consent forms


Neurological Exam (20)
Pubertal Development Scale: Adolescents (10)
Pregnancy Stick Test (5)
Lab test to confirm pregnancy (5)
Urine Sample (5)
Woodcock-Johnson III (20-30)
WASI/DAS + Digit Span+ Coding (50)
Saliva x 2 (5)
Handedness x 2 (5)
CANTAB (35-45) (48 mo +)
CVLT-C or CVLT-II List Learning (30)
Purdue Pegboard Full/Half-Board (5)
Verbal Fluency and/or NEPSY (5)
Brief (10)
JTCI Parent (20-30)
JTCI Adolescent (20-30)
MRI Scanning Procedures (< 90)

Objective 1: Steps for contact

1. InfoUSA provides sample to PSCs (see Appendix A)

2. Mail:
- Introductory Letter to parents (Appendix B)
- Brochure (Appendix C)
- Incentive (fridge magnet)
- Reply Postcard (Appendix D) and business reply envelope (optional)
- Child 'Brain Mapping' Article (optional)

3. Two weeks after mailing, call to administer Brief Telephone Screening Interview (20 min)

4. If Screener OK, Mail:
- CBCL Cover Letter
- Study Description (Appendix H)
- Consent Form
- Consent to audio tape screener
- CBCL (Child Behavior Check List) for child of interest
- Payment form
- 9 x 12 Business Reply return envelope for returning CBCL
- Privacy Act Notification Statement

5. If CBCL, Consent Form, and payment form received:
- Score CBCL
- Mail incentive ($10 gift certificate)
  - If CBCL fail (Any subscale ≥70), include *Ineligible* cover letter (Appendix L-1) with incentive
  - If CBCL pass (All subscales<70), include with incentive:

Next Step cover letter (Appendix M) with
Outline of Full Screener (Appendix N),
Payment form;….then call to schedule Full Telephone Screening Interview using script (Appendix P-1)

6. IF CBCL, etc. NOT received:
- Call to inquire about receipt of CBCL, Consent Form, Payment Form
- Resend CBCL, Consent Form, Payment Form, & return envelope as needed (about 15%)
- When received, score CBCL
- Mail incentive ($10 gift certificate)
  - If CBCL fail (≥70), include *Ineligible* cover letter with incentive

I. If CBCL pass (<70), include with incentive:
1. *Next Step* cover letter with
2. Outline of Full Screener,
3. Payment form(s) (include 2nd payment form in child ≥ 11 for DPS)
   then call to schedule Full Telephone Screening Interview using script

7. Call to administer Full Telephone Screener (Appendix Q)

- Review Telephone Consent (Appendix I), and Consent to audio-tape (Appendix O).
- Administer Full Telephone Screener (20 min). If pass, go on to DISC. If fail, send $10 incentive with *Ineligible* cover letter of explanation (Appendix L-2).
- Administer C-DISC for Parent/DPS-4 for Child greater than 11 (50-60 min; can be administered in-house) (C-DISC instructions Appendix R, DPS-4 instructions Appendix S). If pass, go on to FIGS-MRI. If DISC or DPS not OK, send $20 incentive and *Ineligible* cover letter of explanation (Appendix L-3). If unsure of pass status, review with Principal Investigator or Site Coordinator.
- Administer FIGS-MRI (20 min) (FIGS-MRI instructions Appendix T).
    - IF FIGS OK, Mail incentive ($20 gift certificate) with *Next Step* cover letter (Appendix M-1).
    - If FIGS not OK, mail $20 incentive and *Ineligible* cover letter of explanation (Appendix L-3).

8. If pass Full Screener, C-DISC/DPS,-4 and FIGS-MRI, make Follow Up call to parent to invite family to participate (Appendix U). (Use Phone Message Frequency Guidelines, Appendix F) Set up first MRI appointment with parent.

9. Speak to child of interest using age and gender appropriate scripts to describe study.

10. Send MRI Consents and confirmation letter at least 1 week prior to first MRI appointment.

11. Call parent day before appointment to confirm that the child is in good health and ready to come to the hospital the following day. Inquire about possible viral exposure Also confirm receipt of consent forms, and remind them to bring them to appointment.

12. First MRI appointment, in house testing.

13. Send Thank You letter

14. Send Birthday cards.

15. Send biannual study newsletter. All sites use same newsletter, provided by DCC.

16. Re-screen family?

17. Telephone Contact to schedule 1st follow up appointment at 20 to 28 months from initial MRI.

18. Re-screen family?

19. Telephone Contact to schedule second follow up appointment at 20 to 28 months from 1st follow up MRI.

MAIL / TELEPHONE CONTACTS & SCREENING MEASURES

Appendix A	Candidate Selection and Registration Procedure
Appendix B	Introductory Letter
Appendix C	Brochure
Appendix D	
Appendix E	Brief Telephone Screening Interview
Appendix F	
Appendix G	
Appendix H	Study Description
Appendix I	
Appendix J	CBCL Instructions (1:5-5; 5:6-18 years old; YASR for > 18)
Appendix K	
Appendix L-1	
Appendix L-2	
Appendix L-3	
Appendix M	
Appendix M-1	
Appendix N	
Appendix O	
Appendix O-1	
Appendix P-1	Follow-up CBCL Telephone Call
Appendix P-2	
Appendix Q	Full Telephone Screening Interview
Appendix R	C-DISC Instructions (Can be done on-site)
Appendix S	DPS-4 Instructions (Can be done on-site)
Appendix T	FIGS-MRI Instructions
Appendix U	
Appendices V-Z	
Appendix AA	
Appendix AB	
Appendix AC	
Appendix AD	
Appendix AE	

Appendix A: Candidate Selection and Registration Procedure

- Each PSC is provided:
  1. A geographic zip code map of the site's region.
  2. A summary table of the race and income distribution in their region, based on available 1990 Federal Census information by zip code.
  3. A list of zip codes within 40-60 miles of the site, sorted by:
     a. Miles from the center.
     b. Regional Median Family Household Income.
  4. PSC target accrual tables by Household Income and Race.

- The PSC orders and receives three batches of zipcode lists from InfoUSA by e-mail and floppy diskette and reads them into its database software, e.g. Excel, Access.

- Zipcode list batching gives us some flexibility as well keeps us more up-to-date via InfoUSA's Change of Address revisions, which are monthly. These three batches of zipcodes will be received at months 0, 3, and 6 of the nine-month accrual period, and will be of sizes 3000, 3000, and 4000, respectively.

Each batch will arrive as six files cross-classified by age of child (4.5-5, 6-11 and 12-17 years if Objective 1 only; 0-5, 6-11 and 12-17 years if also Objective 2,) and sex (M, F). The households provided will be balanced by Household Income and Race across the zipcodes within the PSC region, as determined by the regional summary information mentioned in (1) above. There will be duplicate records for households of more than one child, and these duplicates will be listed contiguously in the files from InfoUSA. The PSC will group these duplicate records in order to avoid multiple initial mailings to each such household.

- Some records will not include telephone numbers.
- When ready, the PSC requests a list of random numbers of length equal to the total number of zipcodes in the batch (4000 or 3000) that they will be using to construct their sample.
- The PSC receives the random numbers by email, and these are used with their database to obtain the mailing addresses and telephone numbers for initial contacts.
- The PSC mails out the introductory letter and reply card to candidate families, and flags these families as contacted in their local database.
- The PSC contacts DCC via a web-based interface and provides the candidate's demographic data that is presently available. The DCC automatically assigns two redundant anonymous identifiers, the PSCID and the DCCID (referred to as "Candidate ID" in the Protocol), to the candidate and records the supplied candidate information in the DCC database. No personal information on the candidate is ever sent to the DCC.
- Through a follow-up phone call, the PSC obtains a candidate subject and necessary demographics, including:

  Age of Child
  Sex of Child

- Additional PSC screening as detailed in the Protocol provides the following information which will be entered via web-based interface into the DCC database:

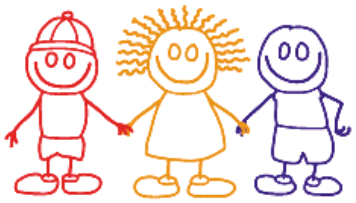
- Ethnicity
- Household Income.
- Parental Education

- After we get well into the nine-month accrual period, re-targeted accruals will be provided to each PSC in order to ultimately match our sample to US proportions globally across all PSCs.

- All subsequent information gathered on the candidate, including results of phone interviews and screening tests, are recorded in and tracked through the DCC database, as well as at the PSC if desired.

- Information on non-responders will also be entered anonymously and tracked through the DCC database, as well as at the PSC if desired.

Appendix B: Introductory Letter to Parents



The MRI study of normal brain development
Sponsored by the National Institutes of Health

Title First Name Last Name
Address
City, State Zip

Dear Title. X:

We are writing to invite you to participate in an important research study sponsored by the National Institutes of Health, being conducted at [site]. The National Institutes of Health (NIH) is the government agency that sponsors most of the medical research in the United States, including ongoing studies of healthy brain development as well as childhood brain disorders.

This new study is known as The MRI Study of Normal Brain Development, and is authorized by federal law (specifically, Title 42, Section 285-j and Title 44, Section 3101 of the United States Code and Section 301 of the Public Health Services Act). The purpose of this study is to understand brain development in typical healthy children, ranging from newborns to teenagers, so that their brains can be compared to those of children who have childhood brain disorders. This information can help us understand the causes of serious childhood conditions like epilepsy, autism, and mental retardation.

Scientists in seven cities around the country are participating. [Site] is inviting families in the [city] area to join the study. Your family was randomly selected based on zip code location and the possible presence of children in the household. A national market research firm provided this information to us.

This study uses the technique of magnetic resonance imaging (MRI). This is a safe and painless method of taking pictures of the brain. There will be no radiation, medication or needles used in our study. In addition to the MRI scanning, your child will be asked to complete some tests of mental ability and psychological development. Your child will also receive a neurological examination by a physician. There are no blood samples. Finally, you will be interviewed about your family history and your child's development. The enclosed brochure further describes the study. We recognize that participating in this study will involve some of your time and energy. You will receive compensation for your time. The benefit to medical science will be much needed information about normal brain development.

This study is completely voluntary. Be assured that there are no penalties if you decide not to respond, either to this letter, or at any stage of the study. If you decide to participate, you will be reimbursed for your time, and receive a written report of your child's psychological testing results. The information you provide will be kept confidential. One likely use of the information is in research on childhood illnesses, where collaborating researchers and contractors may be allowed access to the resulting data. Your privacy and confidentiality will be protected at all times.

In a week or so, a member of our staff will be calling to ask if you are willing to learn more about the study. You will be asked some questions to determine whether or not your child might be eligible to participate. If you do not wish to be contacted, just return the enclosed post card. If you would like to learn more about the study, you may wish to return the post card and let us know convenient times to call you. We've enclosed an article about this study of children's brain development and MRI from the April edition of Child magazine.

We hope you will consider participating in this important study. If you have any questions or concerns, please call our Project Coordinator, [name] at [phone number].

Sincerely,

[Principal Investigator and title]

Appendix C: Brochure

The MRI Study of Normal Brain Development

Sponsored by
The National Institute of Mental Health
The National Institute of Child Health and Human Development
The National Institute of Neurological Disorders and Stroke

Participating Centers

Children's Hospital Boston
Principal Investigator: Michael Rivkin, M.D.
Associate Investigators: Heidelise Als, Ph.D., Gloria B. McAnulty, Ph.D., Robert Mulkern, Ph.D., Deborah Waber, Ph.D.

Children's Hospital Medical Center of Cincinnati
Principal Investigators: William S. Ball, M.D., Anna Weber, Ph.D.
Associate Investigators: Antonius DeGrauw, M.D., Ph.D., Scott Holland, Ph.D.,

Children's Hospital of Philadelphia
Principal Investigator: John Haselgrove, Ph.D.
Associate Investigators: Marsha Gerdes, Ph.D., Molly McDaniel, B.A., Edward Moss, Ph.D., Zhiyue Wang, Ph.D.

University of California, Irvine
Principal Investigator: Pauline A. Filipek, M.D.
Associate Investigators: Jenifer Juranek, Ph.D., Chris Majors, Psy.D.

University of Texas Health Science Center at Houston
Principal Investigator: Michael E. Brandt, Ph.D.
Associate Investigators: Larry Kramer, M.D., Jack Fletcher, Ph.D.

Washington University St. Louis
Principal Investigators: Kelly Botteron, M.D., Robert McKinstry, M.D., Ph.D.
Associate Investigators: C. Robert Almli, Ph.D., Jeffrey Neil, M.D., Ph.D., Richard Todd, M.D., Ph.D.

University of California, Los Angeles
Principal Investigator: James T. McCracken, M.D.
Associate Investigators: Robert Asarnow, Ph.D., Jennifer Levitt, M.D., Arthur Toga, Ph.D.

Data Coordinating Center:

Montreal Neurological Institute
Principal Investigator: Alan Evans, Ph.D.
Associate Investigators: Louis Collins, Ph.D., Gabriel Leonard, Ph.D., Tomas Paus, M.D., Ph.D., Bruce Pike, Ph.D., Alex Zijdenbos, Ph.D.

Harvard University/ McLean Hospital
Associate Investigator: Nicholas Lange, Sc.D.

University of California, Los Angeles
Associate Investigators: John Mazziotta, M.D., Ph.D., Arthur Toga, Ph.D.

Georgetown University
Associate Investigator: Thomas Zeffiro, M.D., Ph.D.

What does it feel like inside the scanner?

Children will be positioned comfortably on a scanning bed that slides into the tunnel-shaped magnet. When the scanner is turned on, it makes humming and knocking sounds. Earmuffs or earplugs will be provided. An intercom system allows the child and technologist to speak to each other at all times.

Parents may accompany their child into the scanning area.

Why is this study being done?

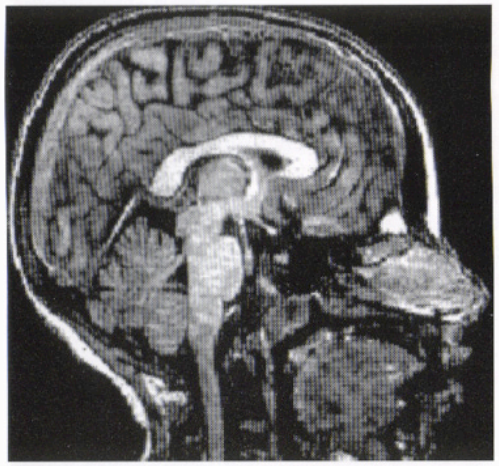
The goal of this study is to learn more about how the brain develops in normal, healthy children and adolescents. By using Magnetic Resonance Imaging (MRI), a safe and painless procedure, changes in the brain can be observed and related to thinking, feeling, and behavior.

This study will enroll approximately 500 children, ranging from infancy to young adulthood, who will be seen at different time points over a six-year period. It will involve seven different sites across the United States as well as a central coordinating center in Montreal, Canada.

The information obtained during the study will provide essential knowledge for scientists for years to come. It can help us understand the causes of serious childhood conditions like psychosis, obsessive-compulsive disorder, epilepsy, autism, and mental retardation.

What is MRI?

MRI, or magnetic resonance imaging, is a way to take pictures of the brain by using a large magnet, radio waves and a computer. The tunnel-like magnet around the subject sets up a strong magnetic field. Radio waves, like those detected by a radio, are transmitted and interact with water molecules in the body that are in "resonance." These water molecules send out signals that the computer turns into images. These images reveal the difference between different types of tissues. The magnetic fields have no known harmful effects. MRI does not use X-rays and is not painful.



MR image from the scan of a 13-year-old.

Who should participate?

Normal, healthy infants, children and adolescents may participate in this study. Children generally enjoy the attention and testing and may be offered a picture of a brain for school projects.

Before the MRI, children and parents will be asked to fill out a form asking if there are any metal or battery-operated devices in their body. Some metal objects are not allowed for safety reasons. Some examples are metal plates, clips, staples, and implants. While it is safe to be scanned with other metal objects such as dental fillings and braces, they may cause distortion in the images.

What will happen during the study?

During the study, children will complete tests that measure memory, attention, language and motor skills. They may be asked to answer questions, solve problems, and do tasks that are similar to video computer games. They will have a neurological examination and parents will be interviewed about their child's development and psychological experiences. Children will undergo MRI scans.

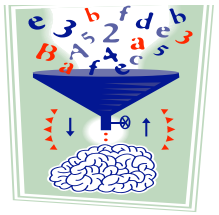
Infants and toddlers will have their behavior and development assessed by experts using playful, colorful objects. Little ones may be scanned during sleep and will be closely attended.

All of the information obtained in this study will be kept private and confidential.

APPENDIX E: BRIEF TELEPHONE SCREENING INTERVIEW (4:6+)

INTRODUCTION:

Random #:_____
Rater #: _____



[If a child answers:]

Hi, my name is _____ from [site]. May I speak with [name of parent]?

[IF mother or father are not home:] I'm calling from [site] to talk to your parents about a research study. What would be a good time for me to call back --is evening better or daytime? **[Time: _____]**

[END CALL]

[IF an adult answers:]

Hi, my name is ____and I'm calling from the MRI Study of Normal Brain Development at [site]. May I speak with [name of parent]? **[___Parent not home, left message]**

[When parent is on the line:]

[IF YES postcard received:] We received your postcard indicating that you would like to learn more about our study. Is this a good time for me to tell you about it? **[IF YES, Continue to Section I Verbal Consent. IF NO, arrange a callback time._____]**

[**IF NO postcard received:]** Did you receive a letter from us in the past few weeks describing a research study?

- **[IF YES has letter]** Is this a good time to tell you more about the study?**YES NO**
  ☛**[IF YES has letter, continue. IF NO, arrange call back time:_____**
- **[IF NO LETTER received:]** The letter described a federally-funded research study of children's brain development. "May I ask, do you have any children living at home between 4 and a half and 18 years old?"
  - [**IF YES, children:]** We'd like to send you another copy of the letter that explains our study. Would that be okay? May I confirm your address? [Give address you have.] Thank you for your time. **[END CALL]**
  - **[IF NO children:]** Okay. We're studying families with children living at home. Thank you for your time. **[END CALL]**

I. VERBAL CONSENT:

As we explained in our letter your family was randomly selected to participate in a research study sponsored by the National Institutes of Health. We are contacting households throughout the [site] area to see if they are interested in participating in this research. We obtained your name from a company that supplies names, addresses, and phone numbers for scientific surveys. This is a voluntary research study and there will be no cost to you for participating in it. In fact, if you or your family decide you are interested you will be reimbursed for your time and effort, depending on which part you complete. Your participation is voluntary. The first part of the study involves asking interview questions over the telephone. May I ask you a few questions to find out if your family is eligible for this part of the study? **[IF YES, continue. IF NO, thank and END CALL]**

All of your responses will be confidential. You may decide to stop answering questions at any time. If you do not wish to answer a question, please let me know. By answering a question, there is no guarantee that your child will participate in the study. If your child is not eligible, the information from your responses will not be kept. If your child is eligible, this information will be kept confidential and we will contact you further about the study.

Signature of Interviewer: _____ Date: _____

1. **"How many children do you have?" _____**
   [If ANY children, continue, if None, thank and end call]

2. "Do you have any children between ages 4 and a half and 18?" ..... **YES NO**
   [If NO children between ages 4 and a half and 18]
   "I'm sorry but this study is focusing on children between 4 and a half and 18 years of age. Thank you very much for your time and I apologize for any inconvenience." **[END CALL]**
   [If YES, continue]

3. "How many of your children **between ages 4-1/2 and 18 years of age** live in the [site] area **with you**?" _____

   ☛ **If at least 1 child lives in the [area], proceed to Section II.**
   ☛ **If NO children live in the [area]:**
   "I'm sorry but this study is focusing on children living in the [site] area. Thank you very much for your time and I apologize for any inconvenience." **[END CALL]**

II. STUDY DESCRIPTION FOR PARENT

4. Thank you**. I'd like to tell you more about this study.**

The National Institutes of Health is sponsoring research that will describe typical brain development in children and teenagers. This research will provide valuable information that may lead to improved methods for diagnosing and treating a variety of children's' health problems. [SITE] was selected as one of the sites to carry out this research. We have a lot of experience studying the brain and child development.

If your family qualifies, the study may include you and one of your children spending a day at [SITE] this year and then coming back two more times over the next five years so we can follow your child's development.

During each visit, we would make pictures of your child's brain using a method called MRI. MRI exams **have no long term risks,** and do **not** involve radiation. Your child would also take a number of tests that measure **cognitive skills,** memory, attention, and motor skills. Some of the tests are similar to video computer games.

Your child will also receive a neurological exam by a physician. In addition, you **would** be interviewed about your child's health, development, feelings, and school experiences.

In this study, we will compensate you and your child for your time and effort. We will also pay for parking, transportation, and meals for you and your child while you are at the university. **You would also get feedback on your child's cognitive testing**. All information that we collect about your child and your family would be kept confidential.

5. Do you think you might be interested in participating? Saying yes now doesn't mean you're agreeing to anything, just that it's okay for me to tell you more..... **YES NO**
   [*Assure them that they are not agreeing to anything now, you are just interested in finding out whether their family might be eligible*.]
   - **[If NO, END CALL]**
   - **[If YES continue]**

First of all, I'd like to ask you a few more questions to see if one of your children might match the characteristics we're looking for.

6. Is that okay?"..... **YES** **NO**
   - **[If NO, END CALL]**
   - **[If YES, continue to Section III.]**

III. Family Information

7. May I ask your full name? _____(place on Post-it note or contact sheet, but not on this screener)

8. How old are you? _____

I'll be asking a few questions about each of your children [or "your child, if only one], such as name, age, and gender, starting with the youngest. [Don't pause, go to Q9.] [It is only necessary to get the age and gender for children over 18 years of age**; names are not necessary.]**

- **DO NOT RECORD NAME OF CHILD ON SCREENER--write on Post-it note in margin.**
- **Twin or multiple birth is exclusionary. If respondent offers information about child being part of multiple birth, discontinue and go to CONCLUDE, but do not ask about multiple births.**

9. What is the name of your youngest child?

a. Is [NAME] a boy or a girl?	M	F
b. How old is [NAME]? **(Don't use as child of interest if under 4.5 year old)**	YRS____	MTHS___
c. Is [NAME] left or right handed?	LEFT	RIGHT

10. And the name of your next youngest child?

a. Is [NAME] a boy or a girl?	M	F
b. How old is [NAME]? **(Don't use as child of interest if under 4.5 year old)**	YRS____	MTHS___
c. Is [NAME] left or right handed?	LEFT	RIGHT

11. And the name of your next youngest?

a. Is [NAME] a boy or a girl?	M	F
b. How old is [NAME]? **(Don't use as child of interest if under 4.5 year old)**	YRS____	MTHS___
c. Is [NAME] left or right handed?	LEFT	RIGHT

12. And the name of your next youngest?

a. Is [NAME] a boy or a girl?	M	F
b. How old is [NAME]? **(Don't use as child of interest if under 4.5 year old)**	YRS____	MTHS___
c. Is [NAME] left or right handed?	LEFT	RIGHT

13. And the name of your next youngest

a. Is [NAME] a boy or a girl?	M	F
b. How old is [NAME]? **(Don't use as child of interest if under 4.5 year old)**	YRS____	MTHS___
c. Is [NAME] left or right handed?	LEFT	RIGHT

14. And the name of your next youngest?

a. Is [NAME] a boy or a girl?
b. How old is [NAME]? **(Don't use as child of interest if under 4.5 year old)**
d. Is [NAME] left or right handed?

M	F
YRS____	MTHS___
LEFT	RIGHT

15. And the name of your next youngest?
a. Is [NAME] a boy or a girl?
b. How old is [NAME]? **(Don't use as child of interest if under 4.5 year old)**
c. Is [NAME] left or right handed?

M	F
YRS____	MTHS___
LEFT	RIGHT

16. And the name of your next youngest?
a. Is [NAME] a boy or a girl?
b. How old is [NAME]? **(Don't use as child of interest if under 4.5 year old)**
c. Is [NAME] left or right handed?

M	F
YRS____	MTHS___
LEFT	RIGHT

IV. IDENTIFY CHILD OF INTEREST FOR STUDY (Child of Interest is Child 1. Ask height and weight for Child 1, then ask height and weight for next two oldest children.)

17. Now I'd like to ask you some questions about [children's names] as possible participants.

	Child 1		Child 2		Child 3		Child 4		Child 5		Child 6	
a. Height?	Ft	In	Ft	In	Ft	In	Ft	In	Ft	In	Ft	In
b. Weight?		LBS		LBS		LBS		LBS		LBS		LBS

** Refer to CDC growth chart for exclusion criteria [I'm pausing briefly to briefly review a growth chart. Thank you for your patience."]

A. Screen all children for Major Disorders/Injuries: [Review Q.18 & 19 for all children below the age of 18 years]

	Child 1	Child 2	Child 3	Child 4	Child 5	Child 6
18. Has **[child names]** ever been diagnosed with a neurological or psychiatric disorder? **(If YES)** What disorder(s)? _____ _____ _____ [Write description and continue. Supervisor will review for exclusion.]	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
19.Does **[child names**] have any chronic illness? **(If YES)** What illness(s)? _____ _____ _____ [Write description and continue. Supervisor will review for exclusion.]	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No

A. **Screen for Major Disorders/Injuries (child of interest): Now I'd like to ask you a few questions about [Child of Interest name.]**

	Child 1	Child 2	Child 3	Child 4	Child 5	Child 6
20.Has **[child names]** ever had a serious head injury? **(IF YES)** What happened? Was he/she knocked unconscious for more than 30 minutes or hospitalized overnight? _____ _____ _____ [Try to determine nature of head injury. If unconscious for more than 30 minutes, discontinue this child and go to back to next youngest child of interest and start again at Question **20**. "May I ask some of the same questions about [name of next child of interest]?"	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
21. Has **[child names]** ever suffered from seizures? **[IF YES**, discontinue this child and go to back to next youngest child of interest and start again at Question **20**. "May I ask some of the same questions about [name of next child of interest]?"] **[All seizures including Febrile or fever seizures are exclusionary]**	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
22. Does **[child names]** have braces or other permanent dental work, **<u>other than</u>** fillings? **Are they planning to get any?** [**IF YES**, **ask about planned date of removal and note:_____** then discontinue and go to back to next youngest child of interest and start again at Question **20.** "May I ask some of the same questions about [name of next child of interest]?"]	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
23. Does [**child names**] have any recent body piercing that cannot be removed <u>for a while</u>, such as new earrings? [**IF YES**, ask for length of time, and make note: _____. Supervisor will determine whether to place on hold.]	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No
24. Does **[child names]** have any permanent piercings that cannot be removed? [**IF YES**, ask for description:] Can you describe that? _____ **[If piercing above chest level**, then discontinue and go to back to next youngest child of interest and start again at Question **20**. "May I ask some of the same questions about [name of next child of interest]?"]	Yes No	Yes No	Yes No	Yes No	Yes No	Yes No

NOTE: Discontinue screening if **≥ 6** children have met **(non-metal related**) Exclusion criteria and go to CONCLUDE.

B. Screen for English Fluency [Child must be fluent, and 1 parent must be fluent]:

25. What is the language spoken most often in your home? _____

- **[If English, skip to Q. 31.]**
- **If other than English, ask:** "Are you fluent in English?" ……..**YES NO**
- **[If YES, skip to Q. 27.]**
  - **[If NO]** Are there other adults living in the household?…… **YES NO**
    - **[If YES]** Can you tell me their first names only and their relationship to you, such as your sister or mother?

      _____

      _____
    - **[If NO other adults, go to CONCLUDE.]**

26. Is he/she ["he/she" being the adults listed above] fluent in English?…….**YES NO**

- **[IF NO adults in the house are fluent in English, discontinue and go to CONCLUDE.]**
- **[IF YES, continue]**

	child 1	child 2	child 3	child 4	child 5	child 6
27. Is [child of interest name] fluent in English?	**YES NO**	**YES NO**	**YES NO**	**YES NO**	**YES NO**	**YES NO**

- **[If NO, ask Q. 28, 29, 30, then go to CONCLUDE.]**
- **[If YES, skip to Q31.**

[Possible probe: "Does [child] have difficulty in school because s/he is not fluent in English?" YES = EXCLUDE]

	child 1	child2	child 3	child 4	child 5	child 6
28. What is [child name]'s first language?						
29. How long has [child name]'s spoken English?						
30. About what percentage of time does [child name]'s speak English at home?	_____%	_____%	_____%	_____%	_____%	_____%

[If 1st child of interest is not fluent in English (Q 27 = NO), ask if next oldest child is fluent in English, Q 27.]

- **[IF YES to Q 27, go back and re-ask Questions 20 through 24 and screen for major disorders/injuries Q 20 through 24. Then skip to Question 28 and continue.]**
- **IF NO to Q 27, ask about next oldest child, and so on, until list of children is exhausted. If no children are fluent in English, discontinue and go to CONCLUDE.]**

31. Do you think that you and [child name] might be interested in **learning** more about this research study and possibly coming to [SITE] to participate?
……..**YES NO**

- **[IF NO, specific child is not interested, ask if next youngest child of interest would be interested, and go back to Question 18 to screen for major disorders and English fluency. If not interested in any further participation, thank and END CALL.]**
- **[IF YES, continue to Section V]**

V. SET UP NEXT STEPS:

It seems like your family may meet the criteria we're looking for. The next step is to mail you a packet of materials about the study. It will include

- a description of the study,
- a standard child development questionnaire that we would like you to complete and return by mail, and
- a payment form, that we would like you to complete and return by mail, and
- a privacy act notification statement, and
- a consent form that fully explains the benefits and risks of the study, which you need to sign and return to us with the questionnaire. You will receive a $10 gift certificate from [name] for completing this step. About 10 days later you would hear back from us.

32. May I send you that packet?……………………………………………**YES** **NO**

[If YES] Continue.
[If NO, thank and END CALL]

33. Could I confirm your mailing address **and correct spelling of your child's name? [note this on Post-it note or contact sheet]**

____

[Note Child of Interests number]: ____________(#1, 2, 3, 4, 5, 6)

34. And is this the best phone number? [If NO, Is there a better number?] **[confirm the best time, otherwise ask, "Would it be best to call in the daytime or evening?" Record on contact sheet next to #.]**

Phone (____) _____________[note this on post-it note or contact sheet]

Thank you for considering this, we really appreciate it. You should receive a packet in the mail in the next few days. Would you like to have our phone number in case you have any questions? That's (xxx) xxx-xxxx, or toll free, 1-xxx-xxx-xxxx. Thank you again for your time. Goodbye.

CONCLUDE (Say ONLY if the respondent declines to participate or there are no children in the household, or there is not a child/parent in the family that might participate, then say) "Thank you for taking the time to talk with me. As with all large research studies of this type, some families are selected to continue to the next phase, and some are not. Sometimes this selection is made at random, and sometimes it is made on the basis of meeting a very specific requirement in the area of interest to the researchers in the study. At this time, we do not anticipate contacting you further for this study. Goodbye."

APPENDIX H: DESCRIPTION OF STUDY

You and your child are invited to participate in a research study conducted by Dr. _____ and his/her colleagues at_____.

The purpose of this research is to learn more about how the brain develops and how this relates to thinking, feeling, and behavior in children and adolescents. In order to learn about brain development, families with children and adolescents in 7 cities in the United States are being contacted and asked to participate in the study. **As a participant in the study your child will receive:**

- **A full neurological exam**
- **Behavioral testing with results provided to parents**
- **An MRI of the brain**
- **Monetary reimbursement for your time and effort**

For the first phase of the study you will be asked about many different aspects of your children's and your family's life. The initial questions will help find out whether your child meets all the special conditions that the children participating in this study are asked to meet.

The second group of questions will then help us to describe in more depth the children who are taking part in the study. Once your child is part of the study he/she will have a Magnetic Resonance Imaging scan (MRI), a brief physical and a neurological examination by a [name of site) physician, evaluation of skills and abilities, and interviews. The MRI scan takes pictures of your child's brain and is considered safe. MRI scans are done everyday on many children in many hospitals all around the country. The medical examination is like the examination that your family doctor would perform. The skills and abilities measures are like what the child would do at school. This visit will take up to 6 hours to complete and will be scheduled at your convenience.

Should you choose to participate in the study, you will be invited back for follow-up sessions at approximately two-year intervals for school-age children and at shorter intervals for infants, toddlers, and preschool children. The purpose of this is to track the development of your child's learning and behavior and the development of the brain. We will also ask you to complete some questionnaires about your child.

We will pay all expenses for travel, parking and lunch. We will also compensate you for your time and effort in participating in the study.

Appendix J: CBCL – Child Behavior Checklist (1:6 – 18:0+)

Materials:

Child Behavior Checklist - CBCL(Achenbach, 2001)
CBCL/1:5-5 questionnaire (parent report for children ages 4:6 to 5:11 years old)
CBCL/6-18 questionnaire (parent report for children ages 6 to 18 years old)
CBCL/YASR questionnaire (young adult self report for ages >18 years old)

Exclusion Criteria:

Score ≥ 70 on any subscale of the CBCL is exclusionary.
A T – Score ≥ 70 on ANY subscale of the CBCL is exclusionary.

Administration Time:

20 minutes (self-administered)

General Instructions:

This test is to be filled out by the parent/young adult.

Scoring:

Form should be scored upon receipt.

The raw scores are to be entered in the database, and subscale scores will be produced.

Appendix P-1: FOLLOW-UP CBCL TELEPHONE CALL (CBCL Scored, OK for study)

1. Hello. This is _____ calling from _____. May I please speak to _____?
   - **If unavailable:** When would be the best time to reach him/her? Thank you.
   - **If available:** Hello Mr/Mrs/Miss/Dr. _____. My name is _____. I'm calling on behalf of [name of PI] about the study we are conducting on brain development in healthy children. We recently received the survey and consent forms you returned. Thank you for returning them so promptly. We've sent you a $10 gift certificate from [ ] as a thank you.

2. We'd like to invite you to participate in the next phase of the study, which involves one or more telephone interviews that take from 20 to 90 minutes, depending on the interview and the family. We will send you a $10 or $20 gift certificate from [ ], depending on the amount of time we spend completing this phase of the study with you.

   Do you have any questions about the interviews or the study in general? [If NO, continue. [If YES, answer questions, then continue.]

3. Does this sound like something you'd like to do? We can schedule the first interview just about any time of day, whenever is convenient for you. [If YES, continue] [If NO, thank and end call.] Or if you like, we can complete the interview right now. [If you go ahead with interview now, be sure to review consent forms with respondent.]

4. [If not now] What day and time would be best for you?

5. We'll call to remind you about the interview the day before.

   Thank you for your time and support.

APPENDIX Q: FULL TELEPHONE SCREENING INTERVIEW (4:6+)

PSC ID#:_____
DCCID#:_____
Rater #:_____
Respondent: Mother
Father

NOTES TO INTERVIEWER:

- Be sure to review consent forms (regular and audio) with participant.
- This questionnaire is used to identify exclusion criteria before enrolling a new subject. A "YES" to any boxed item is an automatic exclusion. If the respondent provides information which is known to be exclusionary, say: *"I am sorry but this study requires us to only include children who have not had this life event. I appreciate the time you have spent with me. Do you have any questions?"* If child is excluded for non-family reasons, stop and return to short screener and screen second child (This may be done for three children in the family)

[IF a child answers the telephone] "May I speak to your mother or father?" If mother or father is not at home, say "I am calling from [site] regarding a research study. I think your mother or father was expecting a call from me now. What would be a good time for me to call back so that I can talk with your mother or father?" **[Time: _____] [CONCLUDE]**

[IF an adult answers:]

Hi, my name is ____and I'm calling from [site]. May I speak with [name of parent]?

[____Parent not home, left message]

I. Introduction

We spoke earlier about the MRI Study of Normal Brain Development, sponsored by the National Institutes of Health. Today I'd like to go through the telephone interview we talked about. Is this a good time for you? The first part of the interview takes about 15 minutes. Before we get started, I need to review the consent forms. Do you have any questions about the study or about the consent forms? We also sent you a list of questions to think about before we got started today. Do you have that handy? **[If not]** Would you like to go get it?

II. Review Consent forms with respondent

III. Screening Questions

I'd like to ask a few more questions to make sure that [name of child] is fully eligible to participate in this project. Are you at a phone where you can have some privacy and talk freely?

1. Has [name of child] been adopted by you, or is he/she your biological child**?" [If adopted, discontinue:** "I'm sorry, because we also need to collect information on the biological parents of a child, adopted children are not eligible. Thank you for your time."**]**
2. Is [name of child]'s biological father [mother] in the home?

   [IF YES, continue]

   [IF NO] Do you have contact with him [her]**? [Try to determine if mother [father] has enough contact to be able to answer questions about his [her] health and history. Example question,** "When was the last time you spoke to him [her]?**]**

_____

[Note: If it is determined that the biological father [mother] is unknown or mother [father] has not had enough contact to answer questions about his [her] health, discontinue:** "I'm sorry. Because we also

need to collect information on both of the biological parents of a child, we won't be able to include your family in our study. Thank you for your time."**]**

IV. Medical/Developmental History

Now I'd like to ask you several questions about [name]'s health and development.

1. What is [child's name] date of birth? _____/ _____/ _____
2. Did you have a chance to check [name]'s height and weight before this call?

2a. How much does [child's name] weigh now? _____lbs
(If don't know, "What's your best guess? And/or
"Would you say they're average height and weight for their age?")
(See standardized CDC growth curve and weight and size chart)

3. How tall is [name]? [If don't know, "What's your best guess"?] _____Ft ____In
2. "Does [name] have any chronic illnesses? **[Colds do not count]**..... . **YES NO**
[IF YES:]
a. What type? _____
b. What kind of treatment has he/she had?_____
5. Has [name] ever been hospitalized?..... **YES NO**
[IF YES:] Why? _____
6. Has [name] ever had surgery?..... **YES NO**
[IF YES:]
a. Why?_____
b. Were any pins or implants used? ..... **YES NO**
[IF YES:] Could you tell me about that?
_____

7. Has [name] ever had an accident or injury resulting in a loss of consciousness? **YES NO**
[IF YES:]
a. Was [name] unconscious or knocked out for more than 30 minutes?.....**YES NO**
b. Can you tell me what happened?_____
_____

8. Has [name] ever seen a neurologist?..... ...**YES NO**
[IF YES:] Why?
_____

9. Has [name] ever had any seizures including during the time when s/he was a baby? **YES NO**
[All seizures, including febrile **or fever** seizures are exclusionary]

10. Has [name] ever had a brain infection such as meningitis? .....**YES NO**
11. Has [name] ever been treated for cancer?.....**YES NO**

[IF YES:] What type of cancer?_____

12. Has s/he ever been treated with chemotherapy or radiation therapy? ……..**YES NO**

13. Does s/he have diabetes? ……**YES NO**

14. Was [name] born with heart disease or did s/he require heart surgery?……**YES NO**
[IF YES:] Can you tell me more about that?

_____

15. Does [name] have a pacemaker in place? …… **YES NO**

16. Was [name] born with any abnormalities of the face or head?……..**YES NO**
[IF YES:] Can you describe that for me?

_____

17. Does [name] have any problems with skin or joints?…….. **YES NO**
[IF YES] What types of problems? **[rheumatological disorders will exclude the child]**

_____

18. Has [name] ever had his/her lead level checked?……**YES NO UNSURE**
    a. What age was his /her level checked? By whom? _____

19. Has [name] ever been treated for lead poisoning? ……**YES NO**

20. Have you ever been told that [name] has a hearing impairment, either by a physician or by the school? …… …**YES NO**

21. Does [name] have a significant problem with his/her eyes such as crossed eyes or problems seeing which require something other than conventional glasses? ……**YES NO**

22. Has [name] ever received or been referred for physical, occupational or language therapy or participated in an early intervention program? ……**YES NO**
[IF YES:] Could you tell me more about that?

_____

23. Has [name] been diagnosed as having a learning or language disorder? ……**YES NO**
[IF YES ask a to e:] a. Could you tell me more about that?_____

_____

b. When did this begin?_____

c. Is this still going on?..... **YES** **NO**

d. Who diagnosed your child with this disorder? Who did h/she see about this?

_____

e. Did h/she have any tests or evaluations?_____

_____

F = Whole Family Excluded—Don't go back to short screener

24. Has [name] ever been in a special education program? .....**YES** **NO**

[IF YES ask a to c:]

a. Could you tell me more about that? _____

_____

b. When did this begin?_____

c. Did h/she have any tests or evaluations?_____

_____

25. Has [name] ever repeated a grade in school? .....**YES** **NO**

26. Has [name] ever been diagnosed with a psychiatric disorder?.....**YES$_F$** **NO**

[IF YES ask a to c:]

a. What was he/she seen for?_____

b. When was that? _____

c. Was there any treatment provided?_____

Some of these questions we may have asked earlier, and we need to confirm them again.

25. Does [name] have dental braces or a permanent retainer?.....**YES** **NO**

26. Does [name] have any metal plates or pins in his/her body?.....**YES** **NO**

27. Does s/he have any non-removable body piercings? .....**YES** **NO**

29a. What prescription medicines has [name] taken during the past year? **[Do not read entire list, these are suggestions only; Circle all that apply]**

Penicillin Benzathine Amoxicillin Augmentin Azithromycin Biaxin Dicloxacillin Septra Cephalexin Erythromycin Lorabid Sulfixsoxazole Bactrim Rifadin Zithromax

Other _____

a. Could you tell me what s/he was taking them for?

_____

[If child of interest is female, over age 9, ask:]

28. Has [name] begun to have her monthly periods? .....**YES** **NO**

[IF YES:] We will conduct a pregnancy test at the time of the MRI appointment, as we do for all young girls or women who are menstruating since we wouldn't want to scan someone who is pregnant, just to be on the safe side.

31. Is your daughter currently pregnant?.....**YES** **NO**

[IF YES:] It is our policy not to scan anyone who might be pregnant, just to be on the safe side. CONCLUDE.

That's all the medical questions I have about [name].

V. Pregnancy, Labor, and Delivery

Now I'm going to ask you some questions about your [her] pregnancy with [child] [about child's mother's pregnancy].

32. Was [name] a full term baby? **[Full term = in the range of 37-42 weeks**].....**YES** **NO**

32a. What was your due date? _____(month/date/year)

32b. Was [name] born within **two** week**s** of the due date?.....**YES** **NO**

[IF NO:]

32b. How many weeks/days early [or late] was he/she born?....._____ days/weeks
[Exclude if **> 3** weeks early**, or > 2 weeks late]**

33. How much did [name] weigh when he/she was born? _____ lbs _____ oz

34. How far along were you [was she] when you [she] found out you [she] were [was] pregnant?
_____weeks

34a. Did you [the child's mother] experience any complications during the pregnancy? ...**YES** **NO**

[IF YES] Can you tell me more about that?

_____

During pregnancy did you [she] have any medical or neurological disorder that required treatment, for example, diabetes, seizure disorder, or cancer? ..... **YES** **NO**

Comments:

_____

36. During pregnancy did you [she] require a blood transfusion?.....**YES** **NO**

37. When you [she] were [was] pregnant, did you [she] require any surgery under general anesthesia?..... **YES** **NO**

38. Were there any significant problems during labor and delivery? .....**YES** **NO**

[IF YES] Can you tell me more about that?

_____

39. Was [name] born by C-section? .....**YES** **NO**

[IF YES:] [If emergent, ask more questions; If routine, then do not exclude.]

a. Why? _____

b. **If unclear, ask: Were you or the infant in distress?**_____

40. When [child] was born, was s/he one of twins, triplets or more? .....**YES** **NO**

41. Did [child] require any specialized medical care after he/she was delivered?..... **YES** **NO**
[IF YES:] Can you tell me more about that?

41a. If received phototherapy – ask number of days of phototherapy:_____days.

42. Did [child] require a stay in the neonatal intensive care unit after birth?.....**YES** **NO**

43. When you [she] were [was] pregnant with [child], did you [she] take any medications? **YES** **NO**
[IF YES:] What were the medications, and how long did you [she] take them?

[INTERVIEWER: DO NOT READ LIST--CODE SILENTLY.]

[Prenatal vitamins (ex. Nestabs, Materna, Natalins, Natabec) How long?_____
[Pre-term labor medications (Terbutaline, Magnesium Sulfate, Procardia) How long? _____
[Hormone supplements (Progesterone) How long? _____
[Over the counter Antihistimines (Tylenol cold, Benadryl etc.) How long? _____
[Antacids (Tums, Rolaids, Gaviscon, Pepsid, Zantac, Tagamet) How long? _____
[Antibiotics (Penicillin, Amoxicillin, Ceclor, Bactrim, Erythromycin) How long? _____
[Herbal supplements **[Specify]:** How long? _____
_____

Other medications **[Specify]**: How long? _____
_____

43a. Did you [she] breastfeed [child]?..... **YES** **NO**
[IF YES]
a. Did you [she] take any medications while you [she] were [was] breastfeeding? **YES** **NO**
b. Can you tell me what medications you [she] were [was] taking?

[INTERVIEWER: DO NOT READ LIST--CODE SILENTLY.]

Prenatal vitamins
Antibiotics (Penicillin, Amoxicillin, Ceclor, Bactrim, Erythromycin)
Antacids (Tums, Rolaids, Gaviscon, Pepsid, Zantac, Tagamet)
Over the counter Antihistamines (Tylenol cold, Benadryl etc.)
Painkillers (Darvon, Percoset, Codeine)
[Specify all]_____
_____
Other, including herbal supplements **[Specify]** _____
_____

44. Did you [the child's mother] drink any alcoholic beverages **during your pregnancy?**
.... **YES** **NO**
[IF NO] skip to Question 46.

45. How many drinks did you [she] usually have in one week?

___ 1 drink
___ 2 drinks
___ 3 drinks **[more than 2 per week is exclusionary]**
___ 4 drinks
___ 5+ drinks

45a. What is the maximum number drinks you [she] had in one week? _____

45b. ***[Ask only if YES to Q43a, breastfeeding.]*** Did you [the child's mother] drink any alcoholic beverages while you [she] were [was] breastfeeding? ..... **YES NO**

[IF NO] skip to Question 46.

45c. ***[Ask only if YES to Q43a and 45b, breastfeeding.]*** How many drinks did you [she] usually have in one week while breastfeeding?

___ 1 drink ___ 3 drinks ___ 5+ drinks
___ 2 drinks ___ 4 drinks

46. Did you [she] smoke while you [she] were [was] pregnant? .....**YES NO**

[IF NO] skip to Question 46d.

46a. On average, How much did you [she] smoke during the pregnancy ?... _____(# of cigarettes per day; pack = 20 cigarettes).....

less than 1/2 pack per day ___greater than 1/2 pack per day__ [1/2 pack or > per day is exclusionary]

46b. What was the usual brand you [she] were smoking? Unkown ____ Specify _____

46c. Did you [she} change your [her] level of smoking significantly during the pregnancy? YES NO

If yes, Describe

_____

46d. Did you [she] use any street drugs such as marijuana or speed while you [she] were [was] pregnant? .....**YES NO**

[IF NO] skip to Question 47.

46e. Did you [she] use any street drugs, like marijuana or speed, after you [she] found out you [she] were [was] pregnant?.....**YES NO**

VI. Demographics

Now I'd like to ask you some more general questions. Again, all your answers are confidential.

47. How many years of school have you completed?

_____ Less than 6th grade
_____ Less than High School
_____ High school
_____ Some college (includes junior college, associates degree)
_____ College
_____ Some graduate level
_____ Graduate Level

48. What about [child name]'s father [or mother]? How many years of school has he [she] completed?

_____ Less than 6th grade
_____ Less than High School
_____ High school
_____ Some college (includes junior college, associates degree)
_____ College
_____ Some graduate level
_____ Graduate Level

49a. How would you describe which ethnic group you belong to? I'll read you the choices, then you can tell me which one applies to you. (Respondent can choose only one of these choices.)

_____ Hispanic or Latino
_____ Not Hispanic or Latino

How would you describe which ethnic group {child}'s father/mother belongs to? I'll read you the choices, then you can tell me which one. (Respondent can choose only one of these choices.)

_____ Hispanic or Latino
_____ Not Hispanic or Latino

50a. How would you describe your race? I'll read you the choices, and you can tell me which apply to you. You may choose one or more categories.

_____ American Indian or Alaskan Native
_____ African American or Black
_____ Asian
_____ Native Hawaiian or Other Pacific Islander
_____ White
_____ [Interviewer, do not read this option, code silently] Subject does not wish to provide part or all of the above requested information.

b. How would you describe {child}'s father/mother 's race? I'll read you the choices, and you can tell me which apply to you. You may choose one or more categories.

_____ American Indian or Alaskan Native
_____ African American or Black
_____ Asian
_____ Native Hawaiian or Other Pacific Islander
_____ White
_____ [Interviewer, do not read this option, code silently] Subject does not wish to provide part or all of the above requested information.

51. **If mother or father African American**, ask -

51a. Do either you/you child's father/mother have sickle cell trait or disease? YES NO
(If disease, Family exclusion; If trait and child's status unkown, Family Exclusion)

51b. **[If trait in either parent],** Does (child of interest) have sickle cell trait? YES NO UNKNOWN

51c. [May need to clarify], Have they been tested? YES NO

52. Now I'd like to ask you to describe your household income. This is the combined income of all adults living in the household. I'll read you some ranges, and you can tell me when to stop.

_____ zero to $5,000
_____ $5,000 to $10,000
_____ $10,000 to $15,000
_____ $15,000 to $25,000
_____ $25,000 to $35,000
_____ $35,000 to $50,000
_____ $50,000 to $75,000
_____ $75,000 to $100,000
_____ $100,000 to 150,000
_____ Over $150,000

VII. Family History

Now I would like to ask you to think about [name]'s immediate family, namely you, the child's [mother/father] and your other children.

53. Without telling me the **names** of any relative, could you tell me whether any parent or biological brothers or sisters of [child] has ever received a diagnosis of the following disorders:

Schizophrenia? **YES$_F$ NO [YES is Exclusion]**
a. What is their relationship to your child?: _____
b. What is their relationship to your child?: _____
c. What is their relationship to your child?: _____

Bipolar or manic depressive disorder? **YES$_F$ NO [YES is Exclusion]**
a. What is their relationship to your child?: _____
b. What is their relationship to your child?: _____
c. What is their relationship to your child?: _____

Major depressive disorder? **YES$_F$ NO**
[Recurrent MDD or Chronic unremitting MDD are Exclusionary]
a. What is their relationship to your child?: _____
b. What is their relationship to your child?: _____
c. What is their relationship to your child?: _____

Obsessive compulsive disorder? **YES$_F$ NO [YES is Exclusion]**
a. What is their relationship to your child?: _____
b. What is their relationship to your child?: _____
c. What is their relationship to your child?: _____

Attention deficit hyperactivity disorder? **YES$_F$ NO [YES is Exclusion]**
a. What is their relationship to your child?: _____
b. What is their relationship to your child?: _____
c. What is their relationship to your child?: _____

Autism? **YES$_F$ NO [YES is Exclusion]**
a. What is their relationship to your child?: _____
b. What is their relationship to your child?: _____
c. What is their relationship to your child?: _____

Tourette syndrome? **YES$_F$ NO [YES is Exclusion]**
a. What is their relationship to your child?: _____
b. What is their relationship to your child?: _____

c. What is their relationship to your child?: _____

Alcoholism? **YES$_F$ NO [YES is Exclusion]**

a. What is their relationship to your child?: _____

b. What is their relationship to your child?: _____

c. What is their relationship to your child?: _____

Thank you very much for your time. Do you have any questions? I will review the information you provided me with my supervisor to determine whether [child] is eligible to participate in this project. May I verify your address? **[Interviewer reads address]**

_____

_____

We'll get back to you within the next few weeks to let you know one way or the other. Goodbye.

***[OR…*If interview clearly indicates NO EXCLUSION CRITERIA then interviewer can proceed with DISC and FIGS.]**

Now I would like to move into another section of the interview that will focus more on your child's feelings and behaviors. This portion of the interview should take about 45-60 minutes. Do you have time to continue at this point? Would you prefer to schedule a different time to complete this?

[If YES, wishes to continue, interviewer should start FIGS or DISC interview. At completion of DISC or FIGS, ask same as above in italics before continuing with remaining interview.]

[If NO, try to schedule a time for the DISC and FIGS.]

Appendix R: Diagnostic Interview Schedule for Children (C-DISC) Test Instructions (7:0+)

IMAN for Windows

Parent Interview

Diagnostic Interview Schedule for Children (D-DISC-4, Shaffer et al., 2003)

- The Parent DISC interview will be administered to parents with children ≥ 7:0 years of age. The Parent DISC interview will always be administered prior to the DPS-4 for parents with children ≥ 11:00 years of age.

Entering a new patient

1. Double click on the CDISC for Windows icon on your computer desktop. The Columbia University logo will appear on your screen and the DISC program will load.
2. Select "Folder" at the top menu bar. Create a new folder with the following convention: Name of site1, Name of site2, etc. Example: Philly1, Philly2, Boston1, Boston2.
   - When naming a Folder **NEVER** use more than 8 characters and **NEVER** use spaces or punctuation
   - **NEVER** "Load" the currently active folder (you may lose data)
3. Select "Patient" at the top menu bar and select "Add"
   - You may forgo the top convention and instead press F4 (both ways will give you the same result)
4. The Info/Patient Record menu opens an information box entitled "Patient Record" that contains the following fields:
   - Name/Sex/ ID #/ Date registered/ Administration (DISC IV P (Parent)/Choose sections (you have the option to omit certain sections and complete them when the parent comes in for the visit)/ Presentation (Clinician assisted or self assisted)—we will always be using clinician assisted
5. Enter the patient information (move around in the fields by using the TAB key or clicking where you want to enter information)
   - Name: Enter the DCC ID#

   NOTE: Be aware that the **name will appear in the individual PAT.ANS and the 'PATIENT' file.** For confidentiality, leave the name blank and identify cases using only the I.D.
   - Sex: Toggle to highlight the appropriate gender. When administering the parent interview the sex entered should be that of the child. This is so that the correct pronoun will be used in the questions, relating to the child and not the informant.
   - ID: Enter PSC ID obtained from DCC database.
   - Date registered: The date will automatically be entered, based on the computer date setting. (If the date on the computer is set wrong, then the incorrect date will be displayed.)
   - Administration: Choose DISC IV-P past year (this is the parent interview)

- Choose sections: The program is configured to include all diagnostic modules in an interview, unless you 'switch' it off. Certain sections some sites may delay until family comes for the in-house visit (uncheck these boxes if your site has decided to wait until the date of the hospital visit):
    i. Specific Phobia
    ii. Selective Mutism
    iii. Elimination Disorders
    iv. Pica
    v. Oppositional Defiant Disorder
    vi. Nicotine Dependence

    ➢ NEED TO SPECIFY HOW TO ENTER PORTIONS OF DATA/INTERVIEW LATER
    The diagnostic modules to be included by default will be listed in the "**Diagnostic Sections"**, **"Sections"** part of the menu box. If they have been "switched-on" to be included in the interview, you will see a green check mark. If they have been "switched-off" the green check mark will not appear and those sections will not be included in the interview.
- Presentation: Default set to 'Clinician assisted'. This does not need to be altered.

6. When all details have been entered click on the **OK** button to bring you back to the 'Folders' screen. Here you will see the subject listed that you have just entered.

7. To access this information after it has been registered, click on "Info" at the top menu bar and select "Patient record". A small box will appear with the following information:
    Patient:
    - Name
    - Age
    - Sex
    - ID code
    - File name

    Interview:
    - Registration date - the date subject details were entered
    - Start date – date when interview was started
    - Completion Date - when interview was completed
    - Total duration – total time taken to administer the interview

<u>Administering an Interview</u>

1. Highlight the subject whom you wish to interview in the 'folder'.

2. On the top menu bar, click on **RUN**, to bring down a menu box.
Click on **ADMINISTER INTERVIEW** or press the **F7** key. The 'Introduction' screen at the beginning of the interview will appear.

3. There are additional instructions for inserting statement into INTRO1: Following the statement, "This interview is made up mostly of questions about the kinds of things (CHILD'S NAME) has been

doing and feeling in the past year – that is, from last (SEASON) up until today." Please insert: *"Please keep in mind that this interview deals with emotions and behaviors that your child may have. Many of the behaviors we ask about are very normal for children that are (CHILD'S NAME)'s age. Saying that your child exhibits a certain behavior does not mean that it is abnormal. Remember, the best answer is a true and honest answer!"*

Answering a Question

A set of possible answers will be displayed on screen after the question.

These include:

1 for 'Yes' and 2 for 'No'

With some questions (e.g., in the impairment section of each diagnosis) you are also given the option to enter:

3 for 'Sometimes/Somewhat'

You can either use the appropriate key on the keyboard to respond, or use the mouse to click on the answer on screen. With either method, the answer you have chosen will turn to red on screen, before you are taken to the next question/section.

In addition, other key code responses are available, but are not displayed on screen.
These include:

7 or 77 for 'Refuse to Answer'
8 for 'Not Applicable'
9 or 99 for 'Don't Know'

There are a few questions in the DISC interview that are 'type ins'.

Moving through the Interview

Keying in a response will take you to the next appropriate question.

In some cases a response is asked for, after which you need to press **[ENTER]**. You can also click on the **[NEXT]** button in the bottom right of the screen.

Alternatively, use the ↑ or → **keys** (You can't move to the next question however, using this method if the current question hasn't been answered.

Returning to the Previous Question

Click on the **[Previous]** button in the bottom left hand corner of the screen.
Or use the ← or '**Backspace**' keys.

Time-Line

During the Introduction module, several questions are asked in order to establish a 'Time-line' of events. During the interview this graph will automatically pop-up on screen whenever there is a time change enquiry in the question.

If the time-line is needed at any other time, the 'Time-line' button at the bottom right of the screen can be pressed.

Interviewer Notes

Used during the interview if the interviewer needs to make a note of anything that the subject wants to add, or to make notes themselves on anything they feel needs reviewing later. This method can also be used to record any program errors you feel may have occurred. Pressing **[ALT] N** will bring up a small box on screen. Enter your comments and then click on the OK button.

The 'note' can later be reviewed in a reconstruction of the interview.

The Note does not appear in the Diagnostic report.

Exiting Before the Interview has been completed

You have the option to **'suspend'** the interview before it has been fully administered, saving all responses entered so far. This will bring you back to the 'folder' screen, where the status of the interview will have been recorded as 'suspended'.

Exiting when the Interview has been completed

After you have entered the response to the last question in the interview, a **'Confirm'** box will appear on screen informing the user that the interview has finished. Clicking on the **OK** button will accept the final answer and bring you back to the folder.

NOTE: Once completed you will be unable to return to the interview.

Exit the C-DISC for Windows Program

After exiting the interview, click on **FOLDERS** in the top menu bar and then click on **EXIT**. This will bring you back to your Desktop.

Administration Options

While administering an interview, the keys **[ALT]M** will bring up the **Administration** menu at the top of the screen.

- *Start Over*

You have the option to start again at the beginning of the diagnostic section or the entire interview. If you start the module again, the previous responses will still be present, and will be indicated in red on the screen.

However, if you re-start the interview, you will totally erase any answers entered for all the diagnostic section/interview. Make sure that this is what you really want to do!

Whichever option is chosen, a '**Confirm**' box will appear on screen before the action is completed.

- *Font*

  It is possible to change the font style and size.

- *Show Timeline/Alt+T*
- *Interviewer Note/Alt+N*
- *Exit*
  An alternative way to exit the interview and return to the folder. If you use this method in the middle of a diagnostic module, the program will not save the responses already entered for that diagnosis. The interview will be suspended, but on returning to the interview you will commence at the first question for the module. The responses for the incomplete diagnoses will have been erased. ***Choose this option if the parent needs to stop the interview but will return to complete it in the future.***
- *Errors*

  There is an internal error checking function in the program. The degree of checking can be regulated through this menu by highlighting and checking the following:

  Select:

  ➡ *Wait for corrections* ***(Select this option)***

  If a value outside the accepted range is entered, a warning message appears stating that the entered value is problematic. You will not be allowed to continue on the next question until the value has been changed.

  ➡ *Suspend/Alt+Q*

  If an open interview needs to be exited with the intention of returning to it at a later date use the **QUIT** menu, to **SUSPEND**. This will close the interview and save the responses to the questions already asked. The status of the interview (i.e. suspended or completed) will be visible within the folder. On returning to a suspended interview the program will start the interview at the last question a response was entered.

  ➡ *Terminate*

BEWARE choosing the option 'Terminate' at this point will lose all patient responses.

Scoring & Reconstructing

- Commands to execute both functions can be found in the **RUN** menu in the top menu bar, i.e.

  Score Interview: To produce diagnostic report

  Reconstruct Interview: To produce the questions asked and the responses entered in the interview

Printing Diagnostic & Reconstructed Reports

1. The default of the program is set to save all reports. Thus, to print the reports, you must alter the configuration setting through the **Configuration** menu located on the top menu bar:

Configure> Options> Scoring or Reconstruct>Send to….

Click on the 'Print' option to change from **'Disk'** and then click on **[OK]**

The C-DISC is now set to print directly from the program. You then must 'instruct' the program to print the report, as follows:

2. Load the source Folder and highlight the interview required.
3. Open the **RUN** menu.
4. Highlight and click on the required operation to be executed, i.e.
   'Score interview' or 'Reconstruct interview'
5. Modify the settings in the **PRINT** box as required.
6. Click on the [OK] button to start printing.

C-DISC Reports

The internal scoring of the C-DISC program produces two types of reports: the Scored/Diagnostic report and the Reconstructed report. The Scored/Diagnostic report indicates the DSM-IV symptoms, criteria and diagnoses endorsed for an individual case. The Reconstruction lists the questions asked and the responses entered during the interview.

In order to view the report you will need to exit the DISC administration program and open the report file from the "Reports" folder.

The Diagnostic report will list all positive diagnoses first, followed by negative and indeterminate. The program scoring is loyal to DSM-IV and the Diagnostic report uses the exact same wording.

Viewing the Diagnostic Report and Reconstruction on Screen

For a quick scan of results without the need to print or save to disk use **INFO**>Interview Results menu as described on page 11 of the CDISC interviewer manual.

Using this option interview results can be reviewed while an interview is in progress if the interviewer believes that there may be a positive exclusion of diagnosis.

After the completion of the interview, the interview results will need to be scored.
The following are Exclusion Criteria that may be identified during this interview:

- Axis I Diagnoses
- Any illicit steroid use
- Any illicit inhalant use

Appendix S: Disc Predictive Scales (DPS-4 Interview) - Test Instructions for Administration (11:0+)

- The DPS-4 is to be administered to all children and adolescents ≥ 11:00 years of age. **(Use the shorter DPS-4 version)**

Opening Up the DPS-4

1. Select the Start button on the bottom left corner of your computer desktop. Click on Programs and highlight Columbia DPS v4.32.
2. The "Welcome to Columbia DISC Screening Program" screen will appear. Click on the Start button in the middle of the screen.
3. A "Supervisor Log On" box will appear. When you initially begin the program you will have to enter the supervisor and choose a password.
    - Press "ALT & S" at the same time. The add/delete option will become available.
    - Click on "Add/Delete Options
    - Type in your name and choose a password
    - Your name will now appear in the Supervisor Name box every time you log on.
4. Click on the supervisor name (your name) and enter your password. Click OK to begin.
5. The "DPS Control Center" box will appear.

Entering a new patient

1. There are three ways to enter/add new patient information:
    a. Click Subject on the top menu bar and select "Add patient."
    b. Type "Control+S"
    c. Click on the box with the stick figure (the first box on the top left of the screen)
2. The add subject box will appear. Enter the patient information. Do not use names. Consult the laptop user guide for entering the DCC and PSC ids into the appropriate fields. Click OK.
3. If you make a mistake, you may edit subject information in two ways:
    a. Click "Subjects" and select "Edit Interview."
    a. You can click on the second stick figure from the left (the stick figure is holding a wrench).

Administering and Scoring the interview

1. In the main DPS control center box, highlight the patient ID who you will be interviewing.
2. There are two ways to add an interview:
    a. Click on "Interviews" and select "Add interview"
    b. Select "Control+A"
3. Enter the relevant information (most of the information will be the default information).
    a. Enter the location where the interview is conducted.
    b. The interview will always be done by computer so you will not need to enter a date.
    c. Select the Language (English).
    d. Select the Informant (youth).
    e. Select the Skip option.
    f. Select the interview module to run: You will always start with the "Disc Predictive Scales (DPSv4.32)." **The DPS-4 Impairment Module (DPS-IM) module only needs to be administered if positives are given in the DISC Predictive Scales section.**

g. You may directly administer the interview or save the information and administer later. The two options are at the bottom of the screen. Most often you'll administer the interview directly.
h. If you choose to save the information, you may administer the interview at a later date. There are three ways to begin a new interview:
i. Click "Interviews" on the top menu part and click "Administer Interview.
i. Type "Control+G"
ii. Click the fourth box from the left on the main DPS control center menu (the icon is a piece of paper).

4. Administer the interview to the child. You may answer the questions by using your computer mouse and clicking on either yes or no. If you need to stop the interview, you may select the stop icon at the bottom of the screen. You may restart at any time.
a. A box will appear on the screen telling you when the interview is finished.
b. If there were no positives endorsed in the interview, you are finished.
a. If there were positives endorsed, check the diagnosis scores of the interview to determine if you need to administer the DPS-IM section or the DISC-Y. See scoring instructions below.

Scoring the DISC Predictive Scales section to determine termination or continuation of the interview

1. Highlight the interview to be scored in the main DPS control box.
2. Click on "Reports" on the top menu bar and highlight "Report for Interview."
3. A box will appear confirming the interview that you would like to score. Click OK if the information is correct.
4. A report file will appear. This is the score report. You may print the report by clicking on the printer icon.
5. Each subgroup category has a "cut off gate" and a "cut off diagnosis". If you receive any scores >0 for the **cut off gate** score but less than the specified **cut off diagnosis** score, then you will need to administer the DPS-4 Impairment Module only (See instructions for DPS-4 Impairment Module administration and scoring). If the cut off diagnosis score in any section is greater than the specified number for that section, then you will need to administer the DISC-Y (see DISC-Y administration and scoring).

Exiting the DPS

1. You may exit the program by clicking "Control+S."

Administering the DISC-Y Modules

- This DISC-Y only needs to be administered if the cut off diagnosis score for any section is greater than the specified number. For example, if a section tells you that the diagnosis gate is ≥ 4, the subject would have to score a 4 or above to have the DISC-Y administered. (unless otherwise noted)
- Check the DISC Predicitve Scales report to determine which sections of the DISC-Y need to be administered. Any section where the diagnosis gate is greater than the specified cut off needs to administered in the DISC-Y.

1. Open the DISC program. Select the pull down "Patient" menu and "Add patient."
2. Fill in the demographic information according to the Laptop user guide instructions, properly entering the PSC and DCC IDs. Enter the current date. Select the DISC-Y version of the interview. In the "Choose Sections" box, all modules are selected by default. Uncheckmark any sections that you do not need to administer. Only administer the sections as specified by the DPS report. You must still administer the Demographics section.
3. Click OK.
4. Highlight the subject of interest and administer the interview.
5. To score the interview, highlight the patient of interest. Select the "Run" pulldown menu and select "Score Interview" and "Clinical report." Name the file accordingly and check the report. Any positive diagnoses that are exclusionary will exclude the child. Intermediate diagnoses will not exclude child.

Appendix T: FIGS-MRI – Family History Interview for Genetic Studies – Year 1 (4:6+)

FIGS; Initiative NSaBDG, 1992; Maxwell, 1992)

- The FIGS is to be administered to parents all children age 4:6 and above.

Materials:

- FIGS interview packet
- Blank paper
- Pedigree symbol and example packet
- Pencil
- Extra General Screening Question Forms
- Extra Checklists for each family member
    - Depression checklist
    - Mania checklist
    - Psychosis checklist
    - Alcohol, nicotine & drug abuse checklist
    - Paranoid/Schizoid/Schizotypal Personality and Pervasive Developmental Disorder Checklist
    - Antisocial Personality Disorder Checklist
    - TIC disorder checklist
    - Obsessive Compulsive Disorder Checklist
    - Attention Deficit/Hyperactivity Disorder Checklist

Administration Time:

- 5-30 minutes

Exclusionary Measure: Family excluded if parent or sibling is found to have any of the following Axis I psychiatric disorders: schizophrenia, bipolar disorder, psychotic disorder, alcohol dependence, OCD, Tourette disorder, recurrent major depression **or chronic major depression > 24 month episode**, ADHD, and PDD.

General Instructions:

1. Before you begin the FIGS you will need to make a pedigree.
A detailed pedigree provides the following for each person: name, sex, age at the time of pedigree drawing, marital status, role in the family, whether living or dead, and if dead, age at the time of death.

The pedigree should include all first-degree relatives **to the child.** Therefore, the pedigree includes the child, siblings (living and dead), and biological parents. Include all siblings when constructing the pedigree. Only full siblings need to be reviewed in (2) and (3) below**. Indicate the family tree for the child of interest. Record no names on the pedigree or interview forms.**

2. Ask the General Screening Questions.

Ask the informant to keep in mind all of the relatives in the pedigree**, including themselves**, as he/she listens to the questions you will read. When you get a positive response to one of the questions, record it directly on the pedigree by the name of the person being described. (You may also indicate positives on the screening sheet.) At this point you are receiving overall, general information and writing notes on the pedigree, being careful to pick up any hints of pathology. Probing for more detail can come later with the Face Sheets and symptom checklists**. (General screening questions, unless otherwise specified, are for individuals age 4:0 and older).**

3. Ask about individual relatives, using a Face Sheet and symptom checklists.

Having completed the General Screening Questions and having noted the responses directly on the pedigree, complete a Face Sheet for each of the child's first-degree relatives. Ask about each one, using a separate Face Sheet for each, whether or not there is any hint of pathology reported by the informant.

If there is any known pathology, you should have detected it while going through the General Screening Questions with the pedigree. As you do a Face Sheet, immediately examine those hints and complete pertinent checklists that were indicated by the screening questions. The checklists ask details of symptoms, number of episodes, duration, age of onset, treatment, and impairment rating.

Complete a symptom checklist for any suspected depression, mania, alcohol or drug abuse, psychosis, or paranoid/schizoid/schizotypal personality. **Symptom checklists should be completed in the following order of priority of each individual reviewed: 1) ADHD, 2) Depression, 3) Mania, 4) Psychosis, 5) Alcohol & Drugs, 6) Nicotine, 7) OCD, 8) Tic Disorder, 9) ASPD, 10) Schizoid Personality/PDD, Schizotypal, Paranoid Personality.**

After the checklists are completed, or if not checklists were indicated, write on the Face Sheet any narrative that may have significance for diagnosis, including that of "normal." The narrative can be one or two sentences describing what the person was like, and if there were any psychiatric or personality problems.

Should you learn of a disorder other than those for which there are checklists, go to question five on the Face Sheet, which allows space for a description of disorders which were not specifically covered and has questions on the age of onset, treatment, and impairment.

Use a checklist only if you have reason to believe that the informant can tell you something. You will know this either by responses to the General Screening Questions or by the narrative you get when doing the Face Sheet. If you start a checklist and find the informant cannot provide details stop using the checklist. **Some checklists are only for certain age ranges, as specified on the checklist.**

If you already have enough information in the initial screening questions for a positive, **exclusionary** diagnosis in a first-degree relative, there is no need to use a checklist. You can stop the interview at that point and exclude the family. If you are unsure about whether a family member

has met a positive diagnosis, continue to complete all appropriate checklists and face sheets on all family members and review with your supervisor or site coordinator.
Scoring: See algorithm. Computer scoring.

IN-HOUSE PROCEDURES (PARENT)

BRIEF
JTCI (parent for children 4:6 and above)
C-DISC (if not completed by phone)
DPS-4 (if not completed by phone)

(BRIEF) BEHAVIOR RATING INVENTORY OF EXECUTIVE FUNCTION (4:6+)

Materials:

- **BRIEF Questionnaire (Behavior Rating Inventory of Executive Function – Gioia, Isquith, Guy & Kenworthy, 2000) (parent version) Do not photocopy. Use original standardization forms.**

Administration Time:

- **10 minutes**

Exclusion Criteria:

Not an Exclusionary Criteria test

General Instructions:

See Manual

Scoring:

See Manual

(JTCI) JUNIOR TEMPERAMENT AND CHARACTER INVENTORY (4:6-14:11) (TCI) TEMPERAMENT AND CHATACTER INVENTORY (15+)

Materials:

Junior Temperament and Character Inventory (JTCI) C.R. Cloninger 1993
Temperament and Character Inventory (TCI) C.R. Cloninger 1993

- **JTCI Questionnaire (parent version)**
  - **Form 2: ages 4:6 – 14:11 years old**
- **TCI Questionnaire (parent version)**
  Form 4: ages 15:00 years old +
- **Pencil**

Administration Time:

- **20-30 minutes**

General Instructions:

See Manual (page 11).

Scoring:

See Manual

IN-HOUSE PROCEDURES (CHILD/ADOLESCENT)

Neurological Exam & Tanner Staging (10:0 and up) (below age 10 at Neurologists discretion) (completed 1st if possible)
Saliva Sampling (2 samples taken between 12:00 – 18:00 p.m.)
Urine Sampling
Urine and Saliva Sample Tracking Form
Pregnancy Testing
Handedness 1 (4:6 – 5:11) Form A (6:00 years old and up) Form B
DAS Core Tests* (4:6 – 5:11 years old)
WASI* (6:0 years old and up)
WISC* (6:0 years old and up)
Coding (7:0 - 16:11 years old; WISC-III) or Digit Symbol (17:00 years old and up; WAIS-R)
Digit Span (6:0 - 16:11 years old WISC-III) or Digit Span (17:00 years old and up; WAIS-R)
Woodcock-Johnson III* (4:6 and up)
Verbal Fluency - NEPSY (4:6 – 18:00+ yrs old)
CVLT-C (4:6 - 15:11 years old; Part A) or CVLT-II (16:0 years old and up; Part A)
CANTAB (4:6 years old and up; First 2-3 subtests)
CVLT-C (Delayed Recall & Recognition) or CVLT-II (Delayed Recall & Recognition)
CANTAB (remaining subtests)
Purdue Pegboard (4:6 – 5:11 years old: Half Board; 6:0 years old to 18+: Full Board)
JTCI (10:00 years old and up)

***REPRESENT SCREENING MEASURES!**
APPLY EXCLUSION/INCLUSION CRITERIA!

PHYSICAL/NEUROLOGICAL EXAMINATION (4:6+)

- **To be administered to children ages 4:6 and over.**

MATERIALS:

- **Examination Form (on following page)**
- **Paper measuring tapes for head circumference**
- **Nellhaus Charts for Head Circumference Measurement (National Center for Health Statistics, 2000; Nellhaus, 1968)**
- **CDC 2000 Charts for Weight and Stature (National Center for Health Statistics, 2000; Nellhaus, 1968)**
- **Snellen E and Snellen Kindergarten Visual Acuity Charts**
- **Hand-held Ball Painted Bright Red**
- **Stop Watch**
- **HB Pencils**

SCORING

Enter raw data in database.

PHYSICAL/NEUROLOGICAL EXAMINATION FORM

A. IDENTIFYING INFORMATION

EXAMINER _____

B. GENERAL FINDINGS

(001) GENERAL PHYSICAL (limited to visual inspection, auscultation of chest for heart and lungs, palpation of abdomen)

Normal	0
Abnormality present but trivial (describe below)	1
Apparent abnormality present (describe below)	2

(002) UNUSUAL FACIAL APPEARANCE

None	0
Present (describe below)	1

(003) MAJOR MALFORMATION

None	0
Present (describe below)	1

(004) HEAD CIRCUMFERENCE (Use paper tape; measure largest OFC; plot on Nelhaus chart)
Circumference _____cm **(005)** %ile for age_____

Describe all items 002-004 not answered with **(006)** _____

(007) HEIGHT (in centimeters to 00.0cm; plot on CDC 2000 curves)
Height _____ cm **(008)** %ile for age_____

(009) WEIGHT (plot on CDC 2000 curves)
Weight _____ kg **(010)** %ile for age_____

C. MOTOR EXAM

(011- 014) HYPERTONIA	**RUE (011)**	**LUE (012)**	**RLE (013)**	**LLE (014)**
None	0	0	0	0
Mild	1	1	1	1
Moderate	2	2	2	2
Severe	3	3	3	3

(015- 018) HYPOTONIA	**RUE (015)**	**LUE (016)**	**RLE (017)**	**LLE (018)**
None	0	0	0	0
Mild	1	1	1	1
Moderate	2	2	2	2
Severe	3	3	3	3

(019- 022) WEAKNESS	**RUE (019)**	**LUE (020)**	**RLE (021)**	**LLE (022)**
5/5	0	0	0	0
4/5	1	1	1	1
3/5	2	2	2	2
1-2/5	3	3	3	3

(023- 032) DEEP TENDON REFLEXES

BICEPS	**RUE (023)**	**LUE (024)**
Normal (1+,2+,3+)	0	0
Clonus	1	1

TRICEPS	**RUE (025)**	**LUE (026)**
Normal (1+,2+,3+)	0	0
Clonus	1	1

BRACHIORADIALIS	**RUE (027)**	**LUE (028)**
Normal (1+,2+,3+)	0	0
Clonus	1	1

QUADRICEPS	**RLE (029)**	**LLE (030)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

PLANTAR	**RLE (031)**	**LLE (032)**
Normal (moot, flexor)	0	0
Extensor	1	1
Not done	ND	ND

(033) TENDON REFLEX ASYMMETRY

None	0
Present	1

(034- 035) ABNORMAL TRUNCAL POSTURE {DYSTONIA}

None	0
Present	1

Describe **(035)** _____

_____

(036- 040) CHOREOATHETOSIS OR DYSTONIA OF LIMBS

	RUE (036)	**LUE (037)**	**RLE (038)**	**LLE (039)**
None	0	0	0	0
Present	1	1	1	1

Describe **(040)**_____

_____

(041- 045) TREMOR

	RUE (041)	**LUE (042)**	**RLE (043)**	**LLE (044)**
None	0	0	0	0
Present	1	1	1	1
Refused	R	R	R	R

Describe (intention, essential etc.) **(045)** _____

_____

(046- 051) TICS

RUE (046)	**LUE (047)**	**RLE (048)**	**LLE (049)**	**HEAD/FACE (055)**
None	0	0	0	0	0
Present	1	1	1	1	1

Describe **(051)**_____

_____

(052- 053) FINGER-TO-NOSE ACCURACY (The examiner holds his/her finger at each of several positions in space, all of which are at 1 arm's length from the subject. The subject is asked to touch successively with one hand first the examiner's fingertip with his/her own index fingertip followed by the subject's nose with the same index fingertip. Each arm should be tested independently.)

- -

	RUE (052)	LUE (053)
Normal	0	0
Dysmetria	1	1

(054- 055) GAIT:ON HEELS {10 Steps} (Performed by the subject by walking on heels with arms held at sides of body. An error is marked for failure to take a step on heel)

Errors	RLE (054)	LLE (055)
0	0	0
1-2	1	1
≥3	2	2

(056- 057) POSTURING OF ARMS DURING PERFORMANCE OF HEEL GAIT (The subject is assessed for a change in arm position from alongside body to a dystonia-like position with performance of this task)

	RUE (056)	LUE (057)
Absent	0	0
Present	1	1

(058- 059) GAIT: ON SIDES OF FEET {10 Steps} (Performed by the subject walking on lateral aspect of feet with arms held at sides of body. An error is marked for failure to take a step on side of foot)

Errors	RLE (058)	LLE (059)
0	0	0
1-2	1	1
≥3	2	2

(060- 061) POSTURING OF ARMS DURING PERFORMANCE OF GAIT ON SIDES OF FEET (The subject is assessed for a change in arm position from alongside body to a dystonia-like position with performance of this task)

	RUE (060)	LUE (061)
Absent	0	0
Present	1	1

(062- 063) GAIT: ON TIP TOES {10 Steps} (Performed by the subject walking on tip-toes elevating heels with arms held at sides of body. An error is marked for failure to take a step on side of foot)

Errors	RLE (062)	LLE (063)
0	0	0
1-2	1	1
≥3	2	2

(064- 065) POSTURING OF ARMS DURING PERFORMANCE OF GAIT ON TIP TOES (The subject is assessed for a change in arm position from alongside body to a dystonia-like position with performance of this task)

	RUE (064)	LUE (065)
Absent	0	0
Present	1	1

(066- 067) TANDEM GAIT (performed by subject walking heel-to-toe for 10 steps. An error is a step off the heel-to-toe line)

Errors	RLE (066)	LLE (067)
0	0	0
1-2	1	1
≥3	2	2

(068- 070) HOPS ON EACH FOOT 10X CONSECUTIVELY WITHOUT PUTTING OTHER FOOT DOWN (The child should hop in place)

	RLE (068)	LLE (069)
Successful on all 10	0	0
Not successful on all 10	1	1
Unable to get into balance on one foot	2	2

Highest number of consecutive hops **(070)** _____ (1- 10)

(071) ROMBERG SIGN (the subject is instructed to stand with eyes closed, arms extended perpendicular to sides of body, and feet touching together along their medial aspects for 20 sec.)

Stable & eyes closed for 20 seconds	1
Completed task with eyes closed but body wavered	2
Lost balance and Stepped out of position	3
Opened eyes during exercise (impersistence)	4

D. CRANIAL NERVES

(072- 073) VISUAL FIELDS TO CONFRONTATION (Test each eye individually while covering the contra lateral eye.)

	R Eye (072)	L Eye (073)
Normal	0	0
Abnormal	1	1

(074-075)) VISUAL ACUITY (Both the Snellen E and Snellen Kindergarten charts are available. Visual acuity is tested with subject standing 20 feet from chart. Each eye is tested separately while the contra lateral eye is gently covered.)

	R Eye (074)	L Eye (075)
Normal (20/40 or better corrected)	0	0
Impaired (worse than 20/40)	1	1

(076- 078) OCULAR MOTILITY (CNs III, IV, VI) (test by holding bright red ball in front of subject. Ask subject to follow the ball with eyes only. Move ball to elicit cardinal positions of gaze).

	R Eye (076)	L Eye (077)
Normal	0	0
Abnormal	1	1

Describe **(078)**_____

(079- 080) STRABISMUS

	R Eye (079)	L Eye (080)
None	0	0
Clearly noticeable esotropia	1	1
Clearly noticeable exotropia	2	2

(081- 083) NYSTAGMUS

	R Eye (081)		L Eye (082)
None	0		0
Present but mild in end gaze	1		1
Circle any seen on lateral gaze:	R	or	L
Jerk sacchades	2		2
pendular	3		3
rotatory	4		4
Not done	ND		ND

Describe **(083)**_____

(084- 085) FACIAL MOVEMENTS-Eyebrow elevation

	R Side of Face (084)	L Side of Face (085)
Normal	0	0
Mildly Abnormal	1	1
Markedly Abnormal	2	

(086- 087) FACIAL MOVEMENTS-Forceful closure of eyes

	R Side of Face (086)	L Side of Face (087)
Normal	0	0
Mildly Abnormal	1	1
Markedly Abnormal	2	2

(088-089) FACIAL MOVEMENTS-Forceful closure of lips

	R Side of Face (088)	L Side of Face (089)
Normal	0	0
Mildly Abnormal	1	1
Markedly Abnormal	2	2

(090-091) FACIAL MOVEMENTS-Forceful lip retraction to expose teeth

	R Side of Face (090)	L Side of Face (091)
Normal	0	0
Mildly Abnormal	1	1
Markedly Abnormal	2	2

(092- 093) PALATE ELEVATION

	R Palate (092)	L Palate (093)
Symmetric	0	0
Mildly Asymmetric	1	1
Markedly Asymmetric	2	2
Not Done	ND	ND

(094) JAW MOVEMENTS (Up and Down)

Normal	0
Abnormal	1
Not Done	ND

(095) JAW MOVEMENTS (Side to Side)

Normal	0
Abnormal	1
Not Done	ND

(096) TONGUE MOVEMENTS

Protrudes and retracts easily	0
Abno0rmal	1
Not Done	2

(097) GAG

Normal	0
Hyperactive	1
Depressed	2
Absent	3
Not Done	ND

E. FINE MOTOR

(098- 099) TAP YOUR THUMB AND FOREFINGER TOGETHER AS FAST AS YOU CAN 20 TIMES (The examiner should demonstrate this first).

	R Hand (098)	**L Hand (099)**
Time	_____	_____
Not done	ND	ND

(100- 101) THUMB-FINGER OPPOSITION (index-middle-ring-little; 5 sets) (The examiner should demonstrate this first and instruct the person do it as fast as s/he can).

	R Hand (100)	**L Hand (101)**
Time	_____	_____
Not done	ND	ND

(102- 103) PAT PALM OF HAND ON THIGH AS FAST AS POSSIBLE 20 TIMES (The examiner should demonstrate this first and instruct the person do it as fast as s/he can. Palm patting is performed while keeping the heel of the palm on the thigh at all times. The child should be seated in a chair that allows the foot to rest comfortably on the floor with the hip and knee flexed at 90°.)

	R Hand (102)	**L Hand (103)**
Time	_____	_____
Not done	ND	ND

(104- 105) ALTERNATE PALM-DORSUM PAT OF THIGH AS FAST AS POSSIBLE 20 TIMES (10 sets of a maneuver consisting of palm pat then hand dorsum pat of thigh for a total of 20 thigh pats. The examiner should demonstrate this first and instruct the person do it as fast as s/he can. The child should be seated in a chair that allows the foot to rest comfortably on the floor with the hip and knee flexed at 90°).

	R Hand (104)	**L Hand (105)**
Time	_____	_____
Not done	ND	ND

(106- 107) TAP FRONT OF FOOT AS FAST AS POSSIBLE 20 TIMES (The examiner should demonstrate this first and instruct the person do it as fast as s/he can. The child should be seated in a chair that allows the foot to rest comfortably on the floor with the hip and knee flexed at 90°. Foot tapping is performed with the heel of the foot on the floor at all times.)

	R Foot (106)	**L Foot (107)**
Time	_____	_____
Not done	ND	ND

(108- 109) HEEL-TOE AS FAST AS POSSIBLE (10 sets of a tapping maneuver in which the floor is first tapped with the ball of the foot and then with the heel of the foot for a total of 20 taps. The child should be seated in a chair that allows the foot to rest comfortably on the floor with the hip and knew flexed at 90°.) (The examiner should demonstrate this first and instruct the person to do it as fast as s/he can).

	R Foot (108)	**L Foot (109)**
Time	_____	_____
Not done	ND	ND

(110) ACTIVITY LEVEL DURING EXAM

Normal, able to sit for tests	0
Excessively quiet	1
Hyperactive, fidgety, gets up/wanders	2

(111) ATTENTIVENESS DURING EXAM

Normally attentive	0
Distractible but can be brought back to task	1

(PDS) PUBERTAL DEVELOPMENT SCALE (4:6+)

Age: <10:0 at Neurologist's discretion; >10:0 – 18+

Objective:

The scientific rationale for using the Pubertal Developmental Scale derives from the necessity to discern the effect(s) of physiologic change in puberty with changes in brain structure and biochemistry.

Materials:

Pubertal Development Scale (Petersen, A.C., Crockett, L., Richards, M., & Boxer, A. (1988).

- **Pubertal Development Scale (questionnaire)**

General Instructions:

This test is administered at the neurologist's discretion. The neurologist performing the neurological examination (or other trained health care professional at one site) will give this questionnaire.

Scoring:

Enter raw data in database.

SALIVA SAMPLING

AGES: 4:6 and up.

Materials:

- **Trident sugarless gum**
- **Adhesive labels-Avery #5260 (Subject height, weight, #, date, time)**
- **15 ml polypropylene centrifuge tube with screw top (Midwest Scientific – Cat. No. 3018Y)**
- **Disposable polypropylene funnel (Fisher Scientific-- Cat. No. 10-320A)**

Procedure:

During the assessment day, all subjects will be requested to provide two separate 1-3 cc samples of saliva at two time points. They should be collected while the subject is relaxed and not after potentially stressful procedures (e.g., MRI). An appropriate time would be before and after behavioral measures and cognitive testing.

Collect Sample 1 around mid-day:

Instruct subject to rinse mouth with water and chew Trident sugarless gum.
Subject should expectorate into a polypropylene funnel into a 10cc polypropylene tube until approximately 1-3 cc is collected.
Cap tube and label with PSC/DCC ID, height, weight, date, and collection time. (use preprinted labels)

- Collect Sample 2 approximately 2-3 hours later, but not less than one hour apart.

NOTE: Ideally, the saliva sampling should occur in the afternoon. If this timing is impossible, late morning (10:00 am or later) is acceptable. Samples should not be collected before 10:00 a.m. or after 6 p.m.) **Remember to note the time of collection.**

Storage:

- **Store at - 20° C to -80° C.**

URINE SAMPLE

AGES: 4:6 and up.

Materials:

- **Adhesive labels-Avery #5260 (Subject height, weight, #, date, time)**
- **Polypropylene 118cc urine collection containers (Fisher Scientific-- Cat. No. 14-375-148)**
- **Disposable inert transfer pipette (Fisher Scientific-- Cat. No. 13-711-9A)**
- **50 ml conical tubes with cap (Fisher Scientific-- Cat. No. 05-538-67)**
- **Urine "Hats" for small children (T-Plex Ind., Inc., 255 Wolfner Drive, St. Louis, MO 63026—Cat.No. 1000100CS)**

Procedure:

Collect urine in container; **please note the time of collection.**
Transfer 10cc aliquot into polypropylene tube
Cap tube and label with PSC/DCC ID, height, weight, date, and collection time
Set aside remaining urine for pregnancy test if required at this visit.

Storage:

- Store at - 20° C to -80° C.

PREGNANCY TEST

AGES: The Pregnancy Test should be administered to females who have begun menses.

Materials:

- **QuickVue manufactured by QUIDEL Corp.**

Phone: 1-800-874-1517 or 1-619-552-1100.

General Instructions:

Follow test administration directions provided by QUIDEL Corp.

Scoring:

- Results are obtained in about 3 minutes
- Enter that test has been administered in Database.

- If test positive, conduct local clinical lab confirmatory test
- Delay MRI until lab test negative

AGES: 4-6 AND UP

Prior to each scan:

- Ensure that the ***MRI Safety Checklist*** is completed and signed by the patient.

File this with other confidential documents.

- Provide a completed ***MR Technologist's Form*** and ensure that the MR tech has it prior to each scan. The information on it needs to be entered at the console in order for the imaging data to be properly identified. *This can either be filed in the subject binder or kept by the MR technologist with his/her records.*

After each scan:

Ensure that a radiologist at your site reviews the scan.

Complete the ***MRI Scan Form*** found in the subject binder and enter the information in the database. *Keep this in the subject binder.*

Report any Adverse Events to the DCC on a monthly basis. This includes any injuries the subject may have suffered during the scan and/or any incidental findings. ***Note that Serious Adverse Events should be reported within 48 hours!***

Adverse event reports should be sent to the attention of:

Rozie Arnaoutelis Fax: 514-398-8952
Email: rozie.arnaoutelis@mcgill.ca

MRI SAFETY CHECKLIST

Today's Date: ____/____/____ Child Age:_____yrs_____mos Tester:_____

This Checklist is applicable to the CHILD undergoing the MRI. However, if a PARENT or PARENTS plan to be with the child in the Scanner Room during the MRI, then questions are also applicable to that parent (or parents). Thus, the items below apply to the child and the parent(s) that will accompany the child in the Scanner Room. For all items that apply, circle "YES" and write CHILD and/or PARENT, as appropriate, next to the item.

Have you / your child ever been injured by any metallic foreign body (e.g., bullets, BB, shrapnel, etc.)? YES NO

If yes, describe:_____

Have you / your child ever had an injury to the eye involving a metallic object (e.g. metallic slivers, shavings, foreign body, etc.)? YES NO

if yes, describe:_____

Are you pregnant or do you suspect that you are pregnant? YES NO

PLEASE INDICATE IF YOU / YOUR CHILD HAVE ANY OF THE FOLLOWING:

	PARENT		CHILD	
Cardiac Pacemaker	YES	NO	YES	NO
Aneurysm Clip(s)	YES	NO	YES	NO
Implanted Cardiac Defibrillator	YES	NO	YES	NO
Any Type of Biostimulator or Neurostimulator	YES	NO	YES	NO
Type:_____				
Any Type of Internal Electrode(s)	YES	NO	YES	NO
Pacing Wires	YES	NO	YES	NO
Cochlear Implants	YES	NO	YES	NO
Other:_____	YES	NO	YES	NO
Implanted Insulin Pump	YES	NO	YES	NO
Swan-Ganz Catheter	YES	NO	YES	NO
Halo Vest or Metallic Cervical Fixation Devices	YES	NO	YES	NO
Any Type of Electronic, Mechanical or Magnetic Implant	YES	NO	YES	NO
Type:_____				
Hearing Aid, Cochlear Implant, Ear Tubes	YES	NO	YES	NO
Any Type of Intravascular Coil, Filter or Stent	YES	NO	YES	NO
Implanted Drug Infusion Device	YES	NO	YES	NO
Any Type of Foreign Body, Shrapnel or Bullet	YES	NO	YES	NO
Pessary	YES	NO	YES	NO

Penile Prosthesis	YES	NO	YES	NO
Diaphragm	YES	NO	YES	NO
Iron Supplements	YES	NO	YES	NO
Tattooed Eyeliner	YES	NO	YES	NO

A small percentage of patients with tattooed eyeliner have experienced transient skin irritation in association with MRI's. You may want to discuss this matter with your physician.

Note that make-up containing metal (e.g., "Glitter"), any type of metal hairpins or hair holders, or analog (dial) watches should NOT be worn in the Scanner Room.

I attest that the above information is correct to the best of my knowledge. I have read and understand the entire contents of this form and I have had opportunities to ask questions regarding the information on form.

_____

Caregiver's Signature Date

_____

PI or Designee Date

MR TECHNOLOGIST'S FORM

Today's Date: ____/____/____ Child Age:_____yrs_____mos

PSC ID:_____DCC ID:_____Tester:_____

This form should be completed by the coordinator and given to the MR technologist prior to each scan.

Important Note to MR Technologist:
In order to ensure confidentiality, all acquired and transferred data should identify subjects **only** by the DCC-ID, PSC-ID, and date of birth.

SUBJECT IDENTIFIERS:

DCC-ID: __ __ __ __ __ __.

PSC-ID: __ __ __ __ __ __ __.

Subject's DOB: _____
MM / DD / YYYY

SCAN VISIT:

VISIT *(circle one)*: 1 2 3

✓ *(indicate scans to be acquired)*

- ☐ Objective 1 MRI
- ☐ Ancillary A: MRS
- ☐ Ancillary A: MRSI
- ☐ Ancillary B: DTI

HANDEDNESS: OBJECTIVE 1: FORM A (4:6 – 5:11)

Handedness: Form A **(Modified from Oldfield (1971). The assessment and analysis of handedness: the Edinburgh Inventory, 9, 97-113).**

ALSO, Foot- and Eye-Use Tests

4:6 – 5:11

Today's Date: ____/____/____ Child Age:_____yrs_____mos

PSC ID:_____ DCC ID:_____ Tester:_____

Parent Report of Hand Typically Used: RIGHT LEFT NO PREFERENCE

Score 'Active' Hand(s)

1. Write your name/"A"/line:	RIGHTLEFT	BIMANUAL
2. Draw a line/circle/box/heart	RIGHTLEFT	BIMANUAL
3. Throw the Ball to Me:	RIGHTLEFT	BIMANUAL
4. Open the Jar:	RIGHTLEFT	BIMANUAL
5. Hammer a/the Peg into the Hole:	RIGHTLEFT	BIMANUAL
6. Put the Lego/Person on Top of the Tower:	RIGHTLEFT	BIMANUAL
7. Place the Missing Piece in the Puzzle:	RIGHTLEFT	BIMANUAL
8. Use the Spoon to Show Me how you Eat:	RIGHTLEFT	BIMANUAL
9. Cut the Paper with the Scissors:	RIGHTLEFT	BIMANUAL
10. Put the Ring around the Rod:	RIGHTLEFT	BIMANUAL

Foot and Eye Use Tests

FOOT USE TEST: Place ball on floor, ask child to "kick the ball" (Score foot used).

RIGHT LEFT

EYE USE TEST: Place telescope on table, ask child to "look at you through it" (Score eye used).

RIGHT LEFT

SCORING

SCORING: Scoring of Handedness uses the Bimanual Laterality Index (BLI; Michel et al., 1985). BLI = (number of tasks with a right-hand-active strategy minus [the sum of the number of tasks with a left-hand-active strategy plus the number of tasks with a bimanual-active strategy]) divided by the square root of the (sum of the number of tasks with a right-hand-active strategy plus number of tasks with a left-hand-active strategy plus the number of tasks with a bimanual-active strategy, i.e., a maximum of 10 tasks). Based on the BLI, Handedness categories are: Right-Handed when the BLI > +1, Left-Handed when the BLI < -1, and Mixed-Handed (i.e., no preference, inconsistent, or ambiguous handedness) when the BLI is between -1 and +1.

Mixed-Handed (i.e., no preference, inconsistent, or ambiguous handedness) can be assessed in two ways:

(1) the magnitude of the BLI (e.g., the higher the BLI score is above +1, the more consistent the bimanual Right-Handedness, and, the closer the BLI score is to zero the greater the degree of bimanual Inconsistent-Handedness)

(2) calculation of the percentage of right-active, left-active, and bimanual-active manipulations (e.g., a high percentage of bimanual-active manipulations, and/or, equal percentages of right-active and left-active manipulations, would indicate a higher degree of Inconsistent Handedness).

Foot and Eye Use Tests: Score as indicated below.

SCORING: HAND, FOOT & EYE

HANDEDNESS SCORING:

Active Hand (Maximum=10): _____ RIGHT _____ LEFT _____ BIMANUAL

Bimanual Laterality Index (BLI):_____ Handedness: RIGHT LEFT MIXED

% Right:_____ % Left_____ % Bimanual:_____

FOOTEDNESS SCORING:

1=Right-Foot Kick 2=Left-Foot Kick

EYEDNESS SCORING:

1=Right-Eye Look 2=Left-Eye Look

1. HAND SCORE TEST,
2. ENTER DATA INTO COMPUTER DATABASE,
3. COMPUTER SCORE,
4. COMPARE HAND SCORING WITH COMPUTER SCORING FOR QUALITY CONTROL!

Reference:
Michel, G.F., Ovrut, M.R., & Harkins, D.A. (1985). Hand-use preference for reaching and object manipulation in 6- through 13-month-old infants. *Genetic, Social and General Psychology Monographs,*111 (4), 409-427.

PROCEDURE

HAND PROCEDURE: Prior to administering the Handedness Task, ask the child's parent which hand the child typically uses to manipulate objects (e.g., draw, write, use a spoon), and record the response. Also, show the form to the parent, and ask if there are any tasks that the child does not have any experience performing. If there are tasks that the child has not performed, the tester should demonstrate those tasks to the child (e.g., "Watch me cut with the scissors.") immediately prior to administering that task. If the child still cannot perform the task, note this on the score sheet, and do not include that task in the scoring of Handedness (see below).

Handedness Tests should be video-taped to aid in scoring. The child should be sitting at a table, and allowed enough time to successfully carry out the tasks listed below. For each task (1 to 10), it is important that the to-be-manipulated object(s) is placed on the table, centered at the child's midline, in front of the child, and within reach of the child. HAVE THE CHILD PLACE THEIR HANDS IN THEIR LAP PRIOR TO STARTING EACH TASK! Circle RIGHT or LEFT on the form for the 'active hand' used to perform each of the tasks. (Note: The 'active' hand is the hand that manipulates and produces the action [e.g., turns the lid of a jar], in contrast to the 'passive' hand, which serves to hold and stabilize [e.g., holds the jar]). For that example, it is also possible to 'hold the jar by the lid' and 'turn the jar'. Nevertheless, the 'turning hand' is still the 'active hand', so be aware of these possibilities. If the child performs a task with both the right and left hands being SIMULTANEOUSLY active (e.g., two-handed throwing of the ball, using both hands to operate the scissors), score BIMANUAL on the form for that task. If the child switches hands during performance of a task, score the first hand used to perform the task (i.e., Do NOT score as Bimanual)

POSITION OF OBJECTS FOR HANDEDNESS TESTING

CHILD'S HANDS IN LAP AT START OF EACH TRIAL

1. **WRITE** Place a sheet of paper at the child's midline (directly in from of the child and within the child's reach), and center the pencil on the sheet of paper with the tip (lead end) of the pencil pointing directly towards the opposite side of the table, and the eraser end (if it has one) of the pencil pointing directly towards the child. Ask the child to write their name, make a letter 'A', or make a 'line', as age-appropriate. The active hand is the hand that does the writing.

2. **DRAW** Same positioning of sheet of paper and colored pencil as above. Ask the child to draw a simple object (e.g., line, circle, box, heart), as age-appropriate, with a colored pencil. The active hand is the hand that does the drawing.

3. **THROW** Ball placed on midline directly in front of child, and within the reach of the child; ask the child to throw the ball to you. The active hand is the hand that throws the ball.

4. **JAR** (with cover lightly screwed on) is placed on its base at the child's midline, directly in front of, and within the reach of the child; ask the child to open the jar. The active hand is the hand that does the turning.

5. **HAMMER (with Peg Holder)** Peg Holder is centered at the child's midline, directly in front of the child, and within the child's reach. The hammer is placed at the child's midline between the Peg Holder and the child, with the handle of the hammer pointing directly towards the child's midline, and the head of the hammer pointing directly towards the Peg Holder. Ask the child to hammer the peg into the hole. The active hand is the hand that pounds with the hammer.

6. **LEGO** Place the Lego tower at the child's midline and directly in front (and within the reach) of the child. Place the 'to be manipulated Lego piece' between the Lego tower and the child. Ask the child to place the person on top of the tower. The active hand is the hand applying the person on the tower.

7. **PUZZLE** Place the puzzle board (with a puzzle piece from the center of the puzzle missing) at the child's midline, directly in front of the child, and within the child's reach. Position the 'to be placed puzzle piece' between the puzzle board and the child. Ask the child to place the missing piece. The active hand is the hand applying the piece to the puzzle.

8. **SPOON** Place the spoon at the child's midline and within the child's reach; the spoon handle should be pointing towards the child, and the spoon bowl pointing directly away from the child. Ask the child to demonstrate how they would use the spoon to eat. The active hand is the hand moving the fork towards the mouth.

9. **SCISSORS** Place a sheet of paper on child's midline (within reach of the child), and center the scissors (non-hand specific) on the sheet of paper with the cutting tip of the scissors pointing directly away from the child, and the scissors handle pointing directly towards the child. Ask the child to demonstrate how they would use the scissors to cut. The active hand is the hand operating (opening and closing) the scissors

10. **RING (with Rod)** Place the Rod on its stand with the rod in the vertical position at the child's midline and directly in front (and within the reach) of the child. Place the 'to be manipulated Ring' between the Rod and the child. Ask the child to put the ring around the rod. The active hand is the hand applying the ring around the rod.

FOOT AND EYE PROCEDURE: As per first page.

HANDEDNESS (OBJECTIVE 1: FORM B) (Ages 6:0 years +)

(Modified from Oldfield (1971). The assessment and analysis of handedness: the Edinburgh Inventory, 9, 97-113).

NOTE: This test will be administered only once.

Instructions

I am going to ask you to show me how you would do some things.

You will have to make believe you are doing some of these things and show me how you would do it.

BE SURE TO HAVE 'HANDS IN LAP' AT THE START OF EACH TASK!

Score:

The score is the total number of activities carried out with each hand where a right-handed response is given a 1 and a left handed response is given a 0.

A score < 7 = non right handed.

HANDEDNESS Form

Materials: Pencil and paper
Directions: I am going to ask you to show me how you would do some things.

You will have to make believe you are doing some of these things and show me how you would do it.

ACTIONS
1. First I want you to write your name on this sheet of paper
2. Use one hand to show me how to use a hammer
3. Use one hand to show me how to throw a ball
4. Show me how to use a toothbrush
5. Point to my nose
6. Show me how to eat with a spoon
7. Show me how you cut with scissors
8. Show me how to drink from a cup
Total

(DAS) DIFFERENTIAL ABILITY SCALES (4:6 – 5:11)

Objective 1
(Ages 4:6 – 5:11)

– !!! SCREENING TEST !!! –
Exclusion Criteria: *GCA Score <70 (less than 70) for Age
****General Conceptual Ability (GCA) Score (M=100, SD=15)***

MATERIALS
DAS (Differential Ability Scales (Elliot, 1990)
DAS Manual, DAS Stimulus Book, DAS Record Form

GENERAL DESCRIPTION
See Manual

DAS VERBAL COMPREHENSION:

Materials: Box of toys Inset tray Nine colored chips

General Instructions:
Refer to page 73 for general information on how to administer the Verbal Comprehension subtest. Follow item-by-item administration instructions presented in the manual, pages 74–77.

Scoring:
Refer to page 73 for instructions on how to score the Verbal Comprehension subtest.

DAS PICTURE SIMILARITIES:

Materials: Booklet 3 Picture Similarities Card

General Instructions:
Refer to page 79 for general information on how to administer the Picture Similarities subtest. Be sure to follow the instructions on page 79 referring to *Teaching items* (Items 11-12). Follow item-by-item administration instructions presented in the manual, pages 79–80.

Scoring:
Refer to page 79 for instructions on how to score the Picture Similarities subtest.

DAS NAMING VOCABULARY:

Materials: Booklet 2

General Instructions:

Refer to page 82 for general information on *Teaching items* (Items 8 – 9), and on when and how to question/query a child. Follow item-by-item administration instructions, pages 83–85.

Scoring:

Refer to page 82 for instructions on how to score the Naming Vocabulary subtest.

DAS PATTERN CONSTRUCTION:

Materials:

6 black-and-yellow crepe foam squares Booklet 2, 9 black-and-yellow plastic blocks, Booklet 1, Stopwatch

General Instructions:

Refer to pages 90-92 for information on the correct methods for presenting the patterns and testing the child, and timing the child's performance using a stopwatch.
Follow item-by-item administration instructions for Sample Items A – C, and Items 1 – 10 on pages 93-97.

Scoring:

Refer to pages 92–93 for information on how to score items on the Pattern Construction subtest.

DAS EARLY NUMBER CONCEPTS:

Materials: Booklet 2

General Instructions:

Refer to page 102 for general information on *Teaching items* (Items 2-3), and on when and how to question/query a child. Follow item-by-item administration instructions presented in the manual, pages 103-107.

Scoring:

Refer to page 102 for instructions on how to score the Early Number Concepts subtest.

See Appendix A for scoring clarification on this item. Appendix A is on p. 418 of the DAS manual (p. 418 is actually near the beginning of the DAS manual, between the first tab and the first solid blue/un-tabbed page).

b) When counting 'Fail' scores in applying the decision point criteria, any score less than 6 for item 1 should be considered a 'Fail'.

DAS COPYING:

Materials: Booklet 1**,** Pencil with eraser, Sheets of paper approximately 10.2 X 12.7 cm (4 X 5 inches), Scoring Templates A and B

General Instructions:

Refer to page 112 for general information on how to administer the Copying subtest. Follow item-by-item administration instructions presented in the manual, page 113.

Scoring:

Refer to pages 114-145 for instructions on how to score the Copying subtest.

WASI: Wechsler Abbreviated Scale of Intelligence (6:0+)

Objective I
(Ages 6:00+)
– !!! SCREENING TEST !!! –

Materials: **WASI (Wechsler Abbreviated Scale of Intelligence (Wechsler, 1999) Manual**
WASI Stimulus Book
WASI Record Form

EXCLUSIONARY CRITERIA:

Full Scale IQ < 70 is exclusionary

General Instructions:

See Manual

Scoring: **Enter raw data in database.**

Table 3.1. Summary of Start, Reverse, Discontinue, and Stop Rules Start Reverse Discontinue Stop Subtest Point Rule Point

WASI - VOCABULARY

*SCREENING TESTS

Materials:
1. WASI Manual
2. **WASI Stimulus Book**
3. **WASI Record Form**

EXCLUSIONARY CRITERIA

Full Scale IQ < 70 is exclusionary

Test Instructions:

For detailed instructions follow manual, pp 54-83

Scoring:

Follow Scoring principles outlined on pp 84-86 of WASI Manual**.**

WASI - BLOCK DESIGN

*SCREENING TESTS

Materials:

II. WASI Manual
III. WASI Stimulus Book
IV. Block Design Blocks (9)
V. Stopwatch
VI. WASI Record Form

EXCLUSIONARY CRITERIA

Full Scale IQ < 70 is exclusionary

Instructions

For detailed instructions follow manual, pp 90-94

Stop: See Manual

Scoring: Enter raw data in computer.

WASI - SIMILARITIES

*SCREENING TEST

Materials:

WASI Manual
WASI Stimulus Book
WASI Record Form

EXCLUSIONARY CRITERIA:

Full Scale IQ < 70 is exclusionary

Instructions

For detailed instructions follow manual, pp 97-99

Scoring: See Manual pp 116-117

WASI – MATRIX REASONING

*SCREENING TEST

Materials:

WASI Manual
WASI Stimulus Book
WASI Record Form

EXCLUSIONARY CRITERIA:

Full Scale IQ < 70 is exclusionary

Instructions

See Manual

Scoring: See Manual pp 121

WISC III – WECHSLER INTELLIGENCE SCALE FOR CHILDREN III: Digit Span & Coding (6:0 – 16:11)

WISC III – CODING:

Materials:

WISC-III Manual (Wechsler Intelligence Scale for Children III (Wechsler, 1991)
WISC-III Record Form

General Instructions:

See Manual

Scoring:

See Manual

WISC - III: DIGIT SPAN

Materials:

WISC-III Manual
WISC-III Record Form

General Instructions:

See Manual

Digits Forward Start

Digits Backward Start

WAIS - R: WECHSLER ADULT INTELLIGENCE SCALE – REVISED
Digit Span & Digit Symbol (17:0+)

DIGIT SYMBOL

Materials:

WAIS-R Manual (Wechsler Adult Intelligence Scale – Revised (Wechsler, 1981)
- **WAIS-R Record Form**

Start: **Ages 17 +**

General Instructions:

See page 84 in manual for instructions.

Scoring:

Use WAIS-R manual (page 85) and the Digit Symbol Scoring Stencil for scoring.

DIGIT SPAN

Materials:

WAIS-R Manual
WAIS-R Record Form

Start: **Ages 17 +**

General Instructions Digit Forward: See directions in manual on page 65.

General Instructions Digit Backward: See directions on page 66 of manual.

Scoring: **Use WAIS-R manual for scoring.**
Enter raw data in database.

WOODCOCK-JOHNSON III: (4:6+)

– !!! SCREENING TEST !!! –

Objective:

Three subtests of this battery are:

- **Letter Word Identification**
- **Passage Comprehension**
- **Math computations.**

These tests will be used to exclude children who may have a Learning Disability.

*EXCLUSIONARY CRITERIA

Any Standard Score < 70 is exclusionary.

Materials:

WJ-III Manual (Woodcock-Johnson III, Woodcock, McGrew, & Mather, 2001)
WJ-III Stimulus Book
WJ-III Record Form

Scoring:

See Manual

LETTER-WORD IDENTIFICATION *SCREENING TEST

*EXCLUSIONARY CRITERIA

Scoring:

See Manual

Suggested Starting Points:

See Manual

CALCULATION *SCREENING TEST

Materials:

Use the Subject Response Booklet for this test.

*EXCLUSIONARY CRITERIA

Scoring:

See Manual

PASSAGE COMPHREHENSION *SCREENING TEST

*EXCLUSIONARY CRITERIA

Scoring:

See Manual

VERBAL FLUENCY (NEPSY - SEMANTIC & PHONEMIC) OBJECTIVE 1

SEMANTIC (4:6 - 21:5 years:months of age)

SEMANTIC & PHONEMIC (7:0 - 21:5 years:months of age)

MATERIALS:

A Developmental Neuropsychological Assessment (NEPSY) 1997; Korkman, M., Kirk, U., and Kemp, S., Psychological Corporation.

- Stop Watch
- Score Sheets
- NEPSY Manual

GENERAL INSTRUCTIONS:

See Manual.

NEPSY – VERBAL FLUENCY
OBJECTIVE 1 (Record Form – Age 4:6 – 21:5)

OBJECTIVE-1
NEPSY/VERBAL FLUENCY
(Scoring Form – Age 4:6 – 21:5)

Today's Date: ____/____/____ Child's Age: _____YRS _____MOS

PSC ID: _____ DCC ID: _____ DOB: ____/____/____ Tester: _____

Time Limit: 60 seconds per item

GENERAL INSTRUCTIONS:

1) **Hand score tests**
2) **Enter Data into Computer database**
3) **Computer score**
4) **Compare hand scoring with computer scoring for quality control**

CVLT-C: California Verbal Learning Test for Children (4:6 – 15:11)

Objective 1:

The CVLT-C will be employed for children ages 5:0 to 15:11 years old.

Materials:

- **CVLT-C Manual (California Verbal Learning Test for Children (Delis, Kramer, Kaplan & Ober, 1994).**
- **CVLT-C Record Form**

General Instructions:

See Manual.

Scoring:

- **Complete manual scoring of summary recall variable (list totals)**
- **Enter in CVLT-C scoring module.**

CVLT-II: California Verbal Learning Test, 2nd Edition (16:0+)

Objective 1:

The CVLT-II will be employed for adolescents 16 years old and up.

Materials:

b. **CVLT-II Manual (California Verbal Learning Test, Delis, Kramer, Kaplan & Ober, 2000)**
c. **CVLT-II Record Form**

General Instructions:

For complete instructions use CVLT-II Manual, pp 7 - 21.

Recognition Delay Interval (Optional)

Please see pp 15 – 16 of CVLT-II Manual for instructions.

Scoring:

- **Complete manual scoring of summary recall variables (list totals).**
- **Enter in CVLT-II scoring module.**

CANTAB: (Cambridge Neuropsychological Test Battery) (4:6 +)

Cambridge Neuropsychological Test Automated Battery (CeNeS, 1998)
Ages: 4:6 - 18:0+

There are cutoffs for children age 4:6 to 7:11 on Spatial Working Memory and the IDED shift

Materials:

Behavioral Laptop Computer
CANTAB software key
Touch-sensitive screen, MicroTouch model
CANTAB for Windows Test Administration Guide

Test Administration:

For Objective 1, CANTAB testing is always to be presented in the following order as programmed in the 'nihpd' battery: (1) Motor Screening, (2) Spatial Span*, (3) Spatial Working Memory*, (4) Big/Little Circle, and (5) Intra-dimensional/Extra-dimensional Shift*. Testing protocols are described below, and the protocols are organized under the following headings to aid in understanding the progression of a given test: (A) Demonstration/Teaching, (B) Practice/Learning, and (C) Testing. The Demonstration/Teaching section describes the standard procedures for how the examiner demonstrates the test to the child, i.e., teaching the child what must be done to complete the task. The Practice/Learning section describes the standard procedures for allowing the child to practice and learn the task. The Testing section describes the actual testing procedure. It is important to follow the scripts and to provide Demonstration and Teaching to the child!

***NOTE: Objective I will be using a cutoff for the Spatial Working Memory, and the Intra-dimensional/Extra-dimensional Shift for children between the ages of 4:6 – 7:11.**

PURDUE PEGBOARD

Half-board at 4:6 - 5:11
Full-Board at 6:0 - 18+

MATERIALS:

PURDUE PEGBOARD (Gardner & Broman, 1979; Tiffin & Asher, 1948)

Purdue Pegboard (Half-board at 4:6 - 5:11, Full-Board at 6:0 - 18+)
50 Pins (Pegs); 25 in left-cup and 25 in right-cup
Stop Watch
Handedness determined prior to testing (i.e., Right or Left Handed)

GENERAL INSTRUCTIONS:

See Manual

(JTCI) JUNIOR TEMPERAMENT AND CHARACTER INVENTORY (4:6-14:11) (TCI) TEMPERAMENT AND CHATACTER INVENTORY (15+)

Materials:

Junior Temperament and Character Inventory (JTCI) C.R. Cloninger 1995
Temperament and Character Inventory (TCI) C.R. Cloninger 1992

- **JTCI Questionnaire (Self version)**
  - **Form 1: ages 4:6 – 14:11 years old**
- **TCI Questionnaire (He/She version)**
  Form 3: ages 15:00 years old +
- **Pencil**

Administration Time:

- **20-30 minutes**

General Instructions:

See Manual (page 11).

Scoring:

See Manual

Quality Confirmation – Behavioral/Neurobehavioral Tests, Interviews, & Neurological Exams

I. Background

This document has been created based on Quality Confirmation (QC) Subcommittee conference calls and follow-up Email discussions. Subsequent revisions have occurred related to group PSC (Pediatric Study Center) conference calls, and discussions between the Clinical Coordinating Center (CCC) and Data Coordinating Center (DCC).

Initial QC subcommittee participants: Kelly Botteron (moderator), C. Robert Almli, Jack Fletcher, Gabriel Leonard, & Robert Asarnow.

II. Principle Domains Covered Under Quality Confirmation (QC) Plan

A. Administration and scoring of all neurobehavioral tests, screening interviews, parent/self report forms, and neurological examinations.
   1. Neurobehavioral Tests: BSID-II, DAS; PLS-3; CANTAB; WASI; Digit Span and Coding (WISC-III & WAIS-R); WJ-III; CVLT; NEPSY-Verbal Fluency; Handedness; Purdue Pegboard.
   2. Screening Interviews: DISC, DPS, FIGS, Telephone Screening Interviews.
   3. Parent/Self Report Forms: CAREY; PSI; CBCL; BRIEF; JTCI.
   4. Neurological Examinations.

B. Standardization of procedural implementation across PSC's
   1. A significant component of QC is the establishment of clear, standardized instructions for test administration and scoring which can be followed in a consistent fashion across PSC sites and testers. This specification and standardization will occur in a large part through instructions provided in the Procedure Manuals, the Testing Tips and Clarifications documents, and the feedback associated with the QC evaluation process.
   2. Investigators on the QC subcommittee will periodically review and update the instructions in the Procedure Manuals and/or Testing Tips and Clarifications documents. (Last update: Spring-Summer, 2004).

C. Initial QC of new raters/testers (see IV. A.).

D. Ongoing QC monitoring of raters/testers (see IV. B.).

E. The QC Plan does NOT include the 'training' of interviewers/testers.

F. All Database Behavioral QC activities will be centralized within the DCC (see IX or VIII).

III. Quality Confirmation: General Procedures

A. The coordination of all Behavioral QC activities will be centralized within the CCC.
   1. All QC materials (e.g., videotapes/audiotapes, paper copies of completed test booklets/score sheets, questionnaire forms, etc.) from the PSC's will be sent to the CCC in a timely fashion, i.e., as soon as possible after completion of testing and scoring, **but no later than two weeks after**

testing. **Please do not hold sets of QC materials to mail in groups, as this will delay the QC review process.**

2. The QC materials submitted to the CCC will be logged, tracked, and monitored under the supervision at the CCC.
3. If QC review will be accomplished at a site other than St. Louis (e.g., Houston), the CCC will forward the appropriate QC materials to the other site for review.
4. Each test (or subtest, as appropriate) sent to the CCC for QC will be rated as:
   a. Passing--defined as ≥ 90% agreement with the standard for item administration and scoring (required for valid data when testing real 'scanned' subjects);
   b. Provisionally Passing--Minor Problems, potentially passing (may or may not yield valid data); or
   c. Administered/Scored Incorrectly--Major Problems, < 90% agreement with the standard for item administration and scoring (invalid data when testing real 'scanned' subjects).
5. Written feedback about administration and scoring performance is provided to each rater/tester by the QC evaluator. This feedback will be provided in the form of checklist review sheets and specific comments. The written feedback will also be forwarded to site's BI and PI (as well as others that PI may designate), and the DCC.
6. Copies of the QC Evaluation checklists and comments will be retained at the CCC.
7. The CCC will enter all QC related data into a QC database to consolidate results for monitoring the overall QC process and procedures.
8. The CCC will also enter individual QC evaluation results into the Examiner Certification QC fields of the Examiner Certification mechanism of the DCC database. The QC fields of the Examiner Certification mechanism will be used to 'flag' the QC performance of individual testers/raters and their associated testing data.
9. Technically incomplete, insufficient or poor video/audio recordings (e.g., image or sound not adequate for accurate evaluation, missing tests or parts of tests) of testing cannot be accurately reviewed. Such situations are rated as "No QC Decision," and the tester/rater will have to redo the testing and recording with additional practice children for submission to the CCC for QC evaluation.
10. If "correctable" errors (e.g., certain scoring errors) are noted during the QC evaluation process, the rater/tester will be required to correct the error(s) on the score sheets/booklets and in the DCC database. The tester/rater will notify the QC evaluator by sending the corrected score sheets/booklets back to the QC evaluator (via FAX or some form of express mail), who will confirm that the correction(s) has been made in the DCC database. If a subject's profile was already sent to the DCC, the tester/rater will need to contact the DCC to request access to the subject's data so that corrections can be made. **Failure to send corrected materials to the QC evaluator and to make required corrections in the DCC database will result in the test (or subtest, as appropriate) being rated, "Administered/Scored Incorrectly." The time allotted to complete this process is one-week following notification, unless there are extenuating circumstances that are approved by the CCC.**

IV. Quality Confirmation – Neurobehavioral Testing

A. Initial QC Process for "New" Neurobehavioral Testers/Raters: The steps below will be followed and completed by each new tester/rater using practice children prior to administering any neurobehavioral testing to real subjects:
   1. Practice children (in contrast to "real subjects") are not officially enrolled in this study and are used for QC purposes, e.g., used to demonstrate a tester's "readiness" to test real subjects (Real subjects are subjects officially recruited and enrolled to be in the study and receive brain scans).

2. Testers/raters must administer the complete, age-appropriate, testing battery to each practice child submitted for QC evaluation. Submission of a partial testing battery (e.g., just the NEPSY and CANTAB) is not acceptable unless requested by the QC evaluator.
3. Age groups: For QC, a tester/rater must administer and submit a complete testing battery with a practice child for each age group that they will be testing for the study. The tester/rater must continue to submit full testing batteries on practice children for a specific age group, until the CCC deems the rater/tester ready to test real subjects within that specified age group.

Objective I (Visit-1)	Objective I (Visit-2 & 3)
a) age 4:6--5:11	a) age 4:6--5:11
b) age 6:0--7:11	b) age 6:0--16:11
c) age 11:0--13:11	c) age >18:0 yrs
d) age >18:0 yrs	

4. If a test on a practice child is QC evaluated as "Administered/Scored Incorrectly," the rater/ tester will test another practice child with the full battery of testing appropriate for that aged child, and submit those QC materials for evaluation. This process must be repeated until the rater/tester is judged to be administering and scoring the test(s) in an appropriate, standardized fashion.
5. When a tester is deemed prepared to test real subjects by the CCC, the rater/tester, BI, and PI at the PSC site will be notified by the CCC that the rater/tester can administer the tests appropriate to the specified age group(s) of real subjects. Once deemed ready to test real subjects, the rater/tester will provide the CCC with QC materials for the first five real subjects tested to complete the initial QC process for new testers/raters, and advance to the status of "Experienced" Tester/Rater.

B. Ongoing QC Process for "Experienced" Testers/Raters: The steps below outline the QC process to be followed by experienced testers/raters for administering any testing to real subjects after completing QC on the first five real subjects.
   1. All experienced raters/testers will participate in the ongoing QC process for the duration of the study**.**
   2. PSC Sites will submit QC materials to the CCC for every 6th real subject (after the first five real subjects) for the ongoing QC evaluation of testers/raters.
   3. In addition, the CCC may randomly request QC materials for the next real subject being tested at a PSC Site; the next real subject being tested by a specific tester/rater, and/or, the CCC may instruct the PSC site to provide QC materials for specific numbers, ages and/or sequences of real subjects (e.g., the next three real subjects). Further, the CCC may request that a tester/rater provide QC materials for testing of practice children.
   4. If a tester does not administer a particular battery of testing during a 4-month interval, the tester/rater must stop testing real subjects and submit QC materials for a complete testing battery for a practice child (for the required age groups). As necessary, the tester/rater will need to continue to submit QC materials on practice subjects for review until the CCC deems that the tester/rater is ready to resume testing of real subjects. Once ready to start testing real subjects, QC materials must be submitted to the CCC and passed for the first two real subjects tested after the 'break in testing real subjects'.
   5. A tester who fails to remain compliant with standardized administration and scoring procedures, as demonstrated by their QC evaluation results, will be referred to NIH and may be required to stop testing real subjects, and provide QC materials on practice children until the CCC deems that sufficient evidence is available to confirm that the deficiency(s) has been corrected.

C. Objective I QC for Visit-2 & Visit-3 – Special Considerations

1. Initial QC process for "NEW" tester/raters is identical to guidelines outlined above (see IV.A)
2. QC Process for "EXPERIENCED" testers/raters:
   a. Prior to re-starting the testing of real subjects for Visits ≥ 2 for Objective I, experienced testers/raters will need to submit QC materials for a complete testing battery on a practice child at 6 years of age or above. If that QC evaluation is passed, the CCC will provide notice that the tester/rater can begin testing real subjects. Then, QC materials need to be provided to the CCC for the first two real subjects tested.
   b. If the QC evaluation of the testing for the practice child is not passed, additional practice subjects will need to be tested and QC materials provided to the CCC for evaluation. This process will continue until the tester/rater is deemed ready to begin testing of real subjects, and when achieved, will require undergoing QC on the first two real subjects tested.
3. Once "new" and "experienced" testers/raters have successfully passed QC for the real subjects (i.e., five for new, two for experienced) for visits ≥ 2, ongoing QC will be conducted for every 6th real subject as described for Visit-1 (see IV. B.)
4. For PSC sites that will be testing real subjects at <6 years of age for Visits ≥ 2, a practice child at <6 years of age must undergo a complete testing battery and the QC materials sent to the CCC for QC evaluation. The tester/rater must continue to submit full testing batteries on practice children <6 years of age until the CCC deems the rater/tester ready to test real subjects within the <6 year age group.
   If the QC with the practice child does not pass, testing of additional practice children and QC will be required until deemed ready to test real subjects by the CCC.

V. Implementation of QC Process

A. Videotapes are digitized and digital copies of relevant sections will be created on CD and sent by the CCC to the appropriate QC reviewer.

B. QC reviewers will review QC materials in a timely fashion and complete checklist comment sheets. The CCC will aim to complete QC reviews within two weeks of receipt of materials from the site. QC reviewer will send materials and evaluation feedback to the CCC for tracking and data monitoring. Results of the QC evaluation are sent to the rater/tester, BI, and PI at the PSC site.

C. CD's of testing will be stored in a locked secure site at the CCC. CDs will be destroyed after the database is finalized (i.e., after four to five years).

D. QC Process: Other Points
1. Demonstration Videotapes/CD's – Demonstration CD's were prepared for a select number of instruments.
2. The QC process will be most effective if the testers/raters send all of the QC materials (including hand scoring) to the CCC within a few of days of testing A SUBJECT/CHILD, but not later than two weeks of testing. The CCC will quickly process the QC materials, send the materials to QC reviewers for their reviews, and finally, provide feedback to the tester/rater about the quality of their testing administration and scoring. The CCC's goal is to complete the QC process within 14 days or less following receipt of the QC materials from the PSC site. It is important to note that any missing or incomplete materials will delay the QC process.

VI. Quality Confirmation -- Screening Interviews

A. Long Screening Telephone Interview- Objective I

1. New Interviewers/Raters
   a. ALL interviewers must submit COMPLETE copies (tapes and paperwork) of their first 5 Long Screener Interviews with families who have consented to participate in the phone interview.
   b. Audiotapes and copies of interview will be forwarded to the CCC where they will be reviewed and evaluated.
   c. Interviews will be considered "non-passing" if there is >1 error in probing/coding exclusions in 5 interviews.
   d. Following review of audio taped interviews, the CCC will provide feedback to the interviewer, Coordinator, BI, and PI.
   e. If the interviews were judged as "non-passing" then the interviewer must provide audiotapes for review of the next 5 interviews.
   f. If errors are identified in interviews, raters may be requested to re-contact families/subjects to complete or clarify specific questions.
2. Ongoing QC Monitoring: 5 additional interviews would be reviewed/edited per interviewer at approximately 4 & 8 month intervals.
3. QC for visits in year-3 and Year-5 will be identical to that outlined above.

B. DISC & DPS Interview- Objective I

1. New Interviewers/Raters
   a. All interviewers must submit 2-3 practice subject/parent interviews.
   b. All SITES must submit their first 5 "real" DISC (parent) interviews and first 5 "real" DPS interviews.
   c. Tapes will be reviewed/recoded
   d. Interviewers must achieve greater than 97% agreement across all diagnoses on 5 interviews to be considered "Passing."
   e. If less than 97% agreement, interviewer must submit 5 more interviews for review.
   f. If errors are identified in interviews, raters may be requested to re-contact families/subjects to complete or clarify specific questions.
2. Ongoing study phase - Every 6th DISC and DPS interview per interviewer taped, reviewed and passed.
3. <u>QC for Visits in Year-2 and Year-4 – Special Considerations</u>
   a. For certified interviewers, the first two DISC-P, DPS, and DISC-Y interviews will be recorded and sent to the CCC. Then every 5th interview will be recorded and sent to the CCC.
   b. For new interviewers, two practice interviews need to be taped, reviewed and passed. Then the first five DISC-P, DPS, and DISC-Y interviews will be taped and submitted to the CCC.

C. FIGS Interview [Objective I and Objective II]

1. New Interviewers
   a. New interviewer will complete FIGS training packet and exercises. These will be returned to the CCC for review.
   b. New interviewers will then complete 5 FIGS and turn in their completed tapes and paperwork.

i. Kappa should be > 0.8 average across all diagnoses on 5 interviews.
ii. Interview procedures should be appropriately followed.

c. If an interviewer fails to "pass," as described above, they must submit their next 5 interviews for review.

d. If interviews meet b) as above, then the interviewer can proceed with study phase.

2. Ongoing study phase
   a. Every FIGS interview will be taped and reviewed/edited.
   b. Editing review feedback will be provided by the CCC.
   c. Audiotapes will be returned to the sites after approximately one year to erase and reuse.
   d. If errors are identified in interviews, raters may be requested to re-contact families/subjects to complete or clarify specific questions.

VIII. Quality Control -- Neurology Exam

A. For initial training and standardization across sites the neurological examiner from each PSC will meet in a central location for a 1-day meeting. Meeting occurred July 11, 2001.
   1. At this meeting the neurologists present assisted in the finalization of the standardized neurological exam. Their suggestions were discussed and reviewed in this group format in order to specify the items to increase reliability of administration across sites.
      a. Following meeting, standardized neurological exam forms were finalized.
      b. Videotapes of the standardized neurological exam for different age groups were created and distributed to the neurological examiners at each PSC.

B. Each PSC will videotape their first exam of each type to be reviewed and receive feedback to assure standardization across sites.
   1. Performance on the exam is passing when >95% of all exam items are administered appropriately.
   2. If the administration of the neurological exam is judged to be insufficient on > 5% of items administered, then the neurology examiner would be required to test additional practice children. Feedback on deficiencies is provided to the examiner and PI at the site.
   3. Examiners with deficiencies will be required to resubmit tapings of additional neurological exams with practice children until passing administration and scoring.

C. QC for visits in year-3 and year-5 will be identical to that described for baseline.

IX. DCC Database Behavioral Quality Control and Feedback Mechanism

Behavioural QC at the DCC is outlined in Figure 1, and the steps are as follow:

1. PSC acquisition of behavioural and MR data.
2. Following the successful upload of MR data, sites will be asked to send a randomly selected hard copy of one in three files to the DCC. This procedure will be applied throughout the study. The list of hard copies requested is available via the RSS Channel link from the database.
3. To promote a candidate's profile from recruitment to the screening stage, sites must enter:

For Objective 1

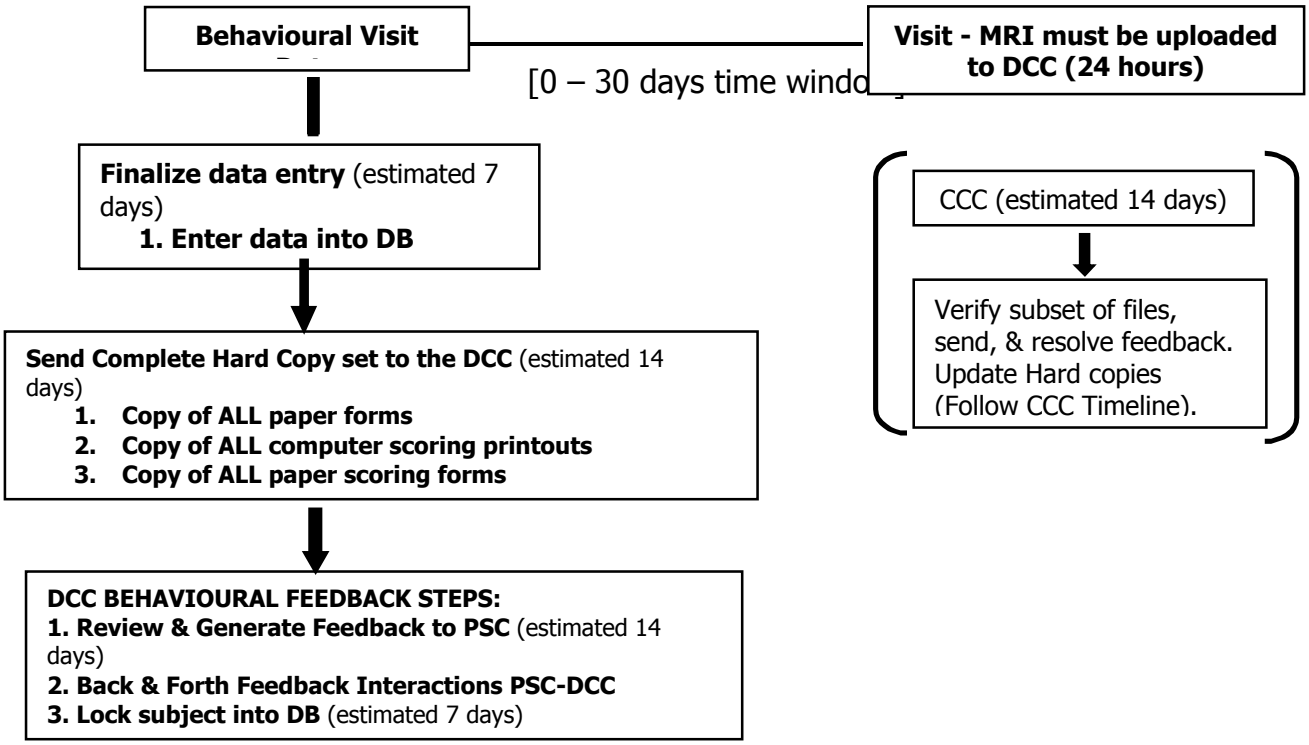
Visit 1 – The date of Screening corresponds to the date of CBCL completion.

Visit 2+ – The date of Screening corresponds to the date of administration of the Full Telephone Screening Interview or the date of CBCL completion (whichever was administered first).

For Objective 2

Visit 1+ – The date when the screening was carried out (it is recommended that the date when The Screening & Exclusion form was completed be used).

Figure 1. QC Timeline.



- Following the initiation of the Screening stage, sites enter all behavioural screening data and upload all screening phase electronic instruments (CBCL; DISC; DPS).
- To promote a candidate's profile from screening to the visit stage, sites must enter the date of the first MRI associated with a given into the DB, regardless of whether the MRI was failed.
- Following the initiation of the Visit stage, sites enter all behavioural data and upload all screening phase electronic instruments (CANTAB; CVLT-II; CVLT-C; DAS; WJ-III).
- DB provides real-time feedback regarding data entry for pen & paper instruments and data upload for electronic instruments, via a DB interface.
- Given that all behavioural data are correctly entered, saved, and marked as complete, a candidate's DB profile can be sent to the DCC by the site PI or his/her designee.
- It is the site's responsibility to ensure that data for candidate profiles are fully entered into the DB before sending a time point to the DCC.
- The QC process begins once the DCC has: a) a hard copy of the candidate's data and b) the DB profile was promoted into the Approval stage. The QC process involves a thorough examination of data found in the candidate's file against data entered into the DB.
- Feedback identifies clerical, input, and scoring inconsistencies or errors (potential scoring errors encountered over the course of DCC behavioural QC are brought to the CCC's attention).
- Errors are identified to the PSC via a DB Feedback mechanism. PSCs can access the candidate profile for which feedback is available and make the appropriate corrections for those instruments for which

data entry inconsistencies have been identified. The DCC also receives automatic DB notification once a PSC makes a change.

- The DCC will maintain a log of the errors identified, feedback interactions with the PSC; and site-specific reports will be periodically generated.
- Following the completion of this interactive process, the candidate will become a study subject.

DCC DATABASE FEEDBACK MECHANISM FOR BEHAVIOURAL DATA

- Once a time point for a candidate's profile has been sent to DCC, the profile is promoted to the "Approval" stage.
- Once in the Approval stage, the data for a candidate's profile can no longer be modified unless feedback from the DCC is available.
- For a subset of profiles, the behavioural feedback mechanism will be used to provide a thorough examination of the data found in the candidate files against data entered into the DB. The subset of one in three profiles to be QC-ed is automatically generated based on received MRI data. The list of hardcopies requested for DCC behavioural QC is available in the DB, via the RSS channel link.
- A colour-coded system has been implemented for all the "Approval" stage candidates for whom the feedback process was initiated by the DCC:

PINK - Feedback was initiated by DCC. PSCs are required to address the feedback.
YELLOW - Feedback answered by PSC, but not finalized. DCC verifies and addresses (if needed) PSC responses.
BLUE - Candidate comments entered by either the PSC or the DCC. Answers are not required.
GREEN - The feedback process is completed.

- Initially, all candidate profiles submitted to the DCC are displayed in the DB as "Approval in Progress."

Following DCC review, profiles will be marked as "Approval Pass," "Approval Failure," or "Approval Withdrawal" (Table 1).

- **Table 1. Approval Stage: Status of Candidate Profiles**

PSC		DCC		
Study Stage	**Status**[1]	**Study Stage**	**Status**	**Behavioural QC**
Screening	Failure	**Approval**[2]	Recycling Bin	No
	Withdrawal		Recycling Bin	No
Visit	Pass	**Approval**	Pass / Failure	Hard Copy / Visual Inspection[3]
	Failure		Recycling Bin	Visual Inspection
	Withdrawal		Recycling Bin	Visual Inspection

[1]The DCC will not QC profiles whose data were failed by PSCs. Visual inspection will be carried out for all the profiles for which a Visit was completed.
[2]This classification does not distinguish the stage at which a profile was marked as a "Failure" or "Withdrawal."
[3]DCC will indicate whether a profile was QC-ed prior to marking it as a "Pass" or "Failure."

After logging into the database, two windows will appear:

1) The Main Database window – allows access to candidate profiles for data entry.

2) A secondary window (QC window) titled "Behavioral Feedback System" – allows access to candidate profiles for which behavioural feedback from DCC is available.

- The Behavioral Feedback System accompanies the main database window, and provides a record of data entry corrections for QC-ed candidate profiles. In effect, available feedback "unlocks" an instrument such that the data can be modified and saved by the PSC.
- In the event where a site believes that data entry errors were made for one or more instruments, they need to contact the DCC, via Mantis, the bug reporting interface, and the DCC will unlock the instruments for which data entry errors were detected. The PSC will access the "DCC unlocked" instruments and make the appropriate corrections.
- The Main Database and the Behavioral Feedback System windows operate in-synch. Therefore, if the Qcis closed window, it will re-emerge when a new page is chosen in the main database screen.
- If the feedback window is not needed, it can be minimized by clicking on the appropriate button found in the top right corner of the computer screen.

Inside the QC window:

- Click on the "visit" link to view general QC feedback for the visit *(e.g., Active Feedback Threads for chosen candidate – Time Point 1).*
- Similarly, click on the "instrument" link for specific QC feedback for an instrument *(e.g., Active Feedback Threads for chosen candidate – Time Point 1 – "Instrument Name").*
- In either screen, a general comment textbox appears. For each candidate, feedback is displayed for every instrument. The error type, QC Class, and activation status of the feedback are indicated.
- A detailed description of the data entry inconsistencies is given under each feedback thread.
- To verify and/or correct each error, access the instrument and click on the "In Progress" button .
    d. Once you are satisfied that corrections are completed, click on the "Save Data" button.
    e. Mark Data Entry as "Complete."
    f. Respond to the appropriate feedback threads.
- Once the PSC replies to feedback, the QC status changes from "Opened" to "Answered" and the colour schema transitions from pink to yellow.
- QC comments are time-stamped line by line in the "Notes" area.
- After the feedback interactions between the DCC and the PSCs have been completed, the QC status of the candidate profile will be marked as "Closed" and the candidate will be promoted to subject status.

EXCLUSIONARY CRITERIA

General Exclusionary Criteria (Objective I)
Tobacco, Alcohol, & Medication Use: Exclusionary Features – Objectives 1 & 2
Appendix AE: Exclusionary Prenatal Medications

General Exclusionary Criteria (Objective 1)

Information Type	Exclusion Criteria	Mother EX	CHILD EX	Family EX
Demographic	Less than 6th grade English reading proficiency of parents			
	Adopted			
Prenatal Factors	Intra-uterine exposures to substances known to alter brain structure or function (drugs, alcohol, medications): Smoking during pregnancy > _ pack per day. Alcohol greater than two alcoholic drinks per week during pregnancy. Medications (see Appendix AE-Exclude Class C, D, X)			
Maternal metabolic conditions during Pregnancy	Phenylketonuria (PKU)			
	Diabetes			
	Preeclampsia (high blood pressure, water retention, too much protein in urine)			
Birth	Less than 37 weeks, greater than 42 weeks gestation			
	Multiple births			
	Born by high forceps delivery			
	Born by vacuum extraction			
Obstetrical complications	Placental abruption			
	General anesthesia for birthing			
	Specialized neonatal care			
	Need for resuscitation			
C-section	C-sections secondary to fetal or maternal medical distress			
Birth weight	Weight (<5th % or >95th % NCHS data)			
Neonatal Factors	Hyperbilirubinemia requiring transfusion (Jaundice)			
	Phototherapy for Jaundice > 2 days			
	Exposure to medications via breast feeding (see Appendix AE-Exclude "Contraindicated")			
Physical/ Medical	Current Height (<5th % NCHS data)			
	Current Weight (<5th % NCHS data)			
	Current Head circumference (<3rd % or >97th % NCHS data)			
	Born with structural abnormalities of head of face			
	Currently pregnant or any pregnancy within 3 months before MRI scan			

Information Type	Exclusion Criteria	Mother EX	Child EX	Family EX
Significant Medical/ Neurological Disorders	History of significant medical or neurological disorder requiring intervention, including but not limited to: Seizure Disorder (including febrile or fever seizures) Diabetes Muscular Dystrophy Myotonic Dystrophy (muscle disease) Sickle Cell Anemia			
	History of closed head injury with loss of consciousness >30 minutes or overnight hospital stay			
	Brain infection such as meningitis: encephalitis			
	Systemic malignancy requiring chemotherapy			
	CNS radiotherapy (radiation treatment for cancer)			
	Tuberous Sclerosis (brain lesion causing seizures, skin lesions)			
	Neurofibromatosis			
	H/o-Lead Poisoning requiring treatment in clinic or intervention, including chelation, change in diet/environment			
	Born with significant heart disease or required heart surgery			
	Steroid use during past 12 months (topical steroid creams; nasal steroids, Or occasional steroid inhalers are OK)			
	Recurrent headaches which were brought to clinical attention (not related To other acute infections or illnesses – sinusitis, influenza, etc.)			
	Rheumatologic disorder (arthritis, lupus, etc)			
	Hearing impairments (requiring treatment/intervention)			
	Visual impairment (strabismus, visual handicap, color blindness, other visual difficulty requiring intervention greater than conventional glasses.)			
Contra indicators For Scanning	Metal implants (braces on teeth, pins) or metal fragments in eye or face			
	Non-removable body piercings			
	Pacemaker or electronic medical implants			

Information Type	Exclusion Criteria (continued)	Mother	Child	Family
Neurologic Exam Factors	Hypertonia: Mild or worse			
	Hypotonia: Mild or worse			
	Weakness: Moderate or worse			
	Ankle clonus in any child over 3 months of age			
	Reflex clonus at any site other than the ankle from birth forward			
	DRT asymmetry			
	Dystonia including congenital torticollis			
	Choreoathetosis			
	Tics			
	Any noted esotropia			
	Any noted exotropia			
	Markedly abnormal facial movement (UMN or LMN)			
	Pendular or rotary nystagmus			
	Strabismus			

Behavioral/ Psychiatric Conditions	Current/past treatment for an Axis I psychiatric disorder (history)			
	Lifetime history of Axis I psychiatric disorder, EXCEPT simple phobia,			
	social phobia, adjustment disorder, oppositional defiant disorder,			
	enuresis; encopresis; nicotine dependency. (by DISC or DPS)			
	Exclusion for: mood disorders; generalized anxiety disorder; separation anxiety disorder; psychotic disorders; schizophrenia; attention deficit hyperactivity disorder; conduct disorder; alcohol abuse/dependence; substance abuse/dependency; eating disorders; tic disorders; obsessive compulsive disorders			
	Current/past physical therapy-if related to medical neurological exclusion			
	Current/past occupational therapy-if related to medical neurological exclusions			
	Current/past treatment for language disorder-may need to request school records			
	Full time special education placement-may need to request school records			
	CBCL scores ≥ 70 on any subscale			
	WASI: Estimated Full Scale IQ rating < 70			

	DAS: Scores below the mean General Conceptual Ability (GCA) that is a score of < 70; M = 100; SD = 15			
	WJ-III: Achievement Scores < 70 on any subscale			
	PLS-3: LSS Scores < 70; M=100; SD = 15			
Temporary Exclusion Factors	Braces			
	Pregnancy			
	New/Temporary Body Piercings			
Family History (first degree relatives)	Axis I psychiatric disorder (s) Schizophrenia Bipolar Disorder Psychotic Disorder Alcohol Dependence Substance Dependence (not nicotine) OCD Tourette Disorder Recurrent Major Depression or MDD episode ≥ 24 months ADHD PDD Antisocial Personality Disorder			
	Inherited neurological disorder			
	Mental retardation due to non-traumatic events Sickle Cell trait in parent (unless child documented not to have Sickle trait)			

Appendix AF: Exclusionary Prenatal Medications

Category A: Controlled human studies have demonstrated no fetal risk.

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Levothyroxine	Levoxyl,Synthroid	Thyroid Agent	Compatible	
Pyridoxine			Compatible	
Thyroid hormone			Compatible	
Vitamin A			Compatible	X in high doses
Vitamin D			Compatible	Also classified D

Category B: Animal studies indicate no fetal risk and no well-controlled human studies have been conducted, or animal studies demonstrated an adverse effect that was not confirmed in controlled human studies.

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Acetaminophen		Analgesic	Compatible	
Amiloride	Midamor	Potassium Sparing Diuretic	No data	First trimester exposure resulted in two fold increase in major birth defects, however sample size was 28
Amoxicillin	Amoxil,Trimox	Antibiotic	Compatible	
Amoxicillin/ Clavulante	Augmentin	Antibiotic, Penicillin	Compatible	
Amphotericin B	Amphocin	Antifungal	No data	
Ampicillin		Antibiotic	Compatible	
Azithromycin	Zithromax	Anti-infective	Compatible	
Aztreonam	Azactam	Antibiotic	Compatible	No human data; no teratogenic effects in animal studies
Bupropion	Wellbutrin,Zyban	Antidepressant	With caution	
Buspirone	Buspar	Anxiolytic, Sedative,Hypnotic	With caution, may be of concern	
Caffeine		Stimulant	Compatible when not used in excess	

Cefprozil	Cefzil	Antibiotic, Cephalosporin	Compatible	
Cefuroxime	Ceftin	Antibiotic, Cephalosporin	Compatible	
Cephalexin	Keflex, Keftab	Antibiotic, Cephalosporin	Compatible	
Cephalosporins			Compatible	
Cetirizine	Zyrtec	Antihistamine	Not compatible according to drug manufacturer	
Chlorpheniramine	Efidac,Teldrin	Antihistamine	Compatible	
Cimetidine	Tagamet	Treatment of Peptic Ulcer	Compatible	
Clindamycin	Cleocin	Antibiotic	Compatible	
Clopidogrel	Plavix	Oral Antithrombic Agent	Compatibility unknown	

Category B: Animal studies indicate no fetal risk and no well-controlled human studies have been conducted, or animal studies demonstrate an adverse effect that is not confirmed in controlled human studies.

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Clotrimazole	Lotrimin,Mycelex	Topical Antifungal	No data	
Cloxaxillin	Cloxapen	Antibiotic	Compatible	
Cromolyn Sodium		Antiasthmatic	No data	
Cyclobenzaprine	Flexeril	Skeletal Muscle Relaxant	Compatibility unknown	
Cyproheptadine	Periactin	Antihistamine	Compatible	
Desmopressin			No data	
Diphenhydramine	Benadryl	Antihistamine	Compatible	
Doxylamine		Antihistamine	No data	
Erythromycin			Compatible	
Ethambutol			Compatible	
Famotidine			Compatible	
Fluoxetine	Prozac	Antidepressant	No data	
Guanethidine	Ismelin	Antihypertensive Agent	Compatible	
Hydrocodone	Vicodin	Narcotic Analgesic	No data	Also classified D
Hydromorphone	Dilaudid	Narcotic Analgesic	Compatible	Also classified D

Ibuprofin	Advil,Motrin	Nonsteroidal Antiinflammatory Agent	Compatible	May inhibit labor if used near term
Imiquimod			No data	
Indomethacin	Indocin	Nonsteroidal Antiinflammatory Agent	Compatible	Also classified D, may inhibit labor if used near term
Insulin			Compatible	
Ipratropium	Atrovent	Antimuscarinic	Compatibility unknown	No adequate human studies
Isosorbide Mononitrate	Imdur	Vasodilating Agent	Compatibility unknown	
Lansoprazole	Prevacid	Control of Stomach Acid	Compatibility unknown	
Lidocaine			Compatible	
Lindane			Alternate feeding method required for four days after exposure	
Loperamide			Compatible	
Loracarbef	Lorabid	Antibiotic	No data	
Loratadine	Claritin	Antihistamine	Compatible at standard dose	
Leukotriene Receptor Antagonists	Zafirlukast, Montelukast	Antiasthmatic	No data	
Magnesium			Compatible	
Meclizine			No data	
Meperidine		Narcotic	Minimal dose	Also classified D

Category B: Animal studies indicate no fetal risk and no well-controlled human studies have been conducted, or animal studies demonstrate an adverse effect that is not confirmed in controlled human studies.

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Mesalamine			With caution	
Metformin	Glucophage	Blood Glucose Regulator	Contraindicated	
Methadone		Narcotic	With caution	Also classified D

Methyldopa		Antihypertensive	Compatible	
Metoclopramide	Reglan	Treatment of emesis, gastric reflux, and gastroparesis	No data, increases milk production	
Metronidazole	Flagyl, Protostat	Antiinfective Agent, Antiprotozoal, and Antibacterial	Contraindicated, discontinue feeding 24 hours after last dose	
Miconazole			Compatible	
Morphine		Narcotic	Compatible, inhibits milk ejection	Also classified D
Naproxen	Naprosyn,Anaprox	Nonsteriodal Antiinflammatory	Compatible	May inhibit labor if used near term
Nitrofurantoin	Furadantin, Macrodantin	Urinary Antiinfective	Compatible	
Nizatidine	Axid	H2-Receptor Antagonist	Compatible	
NSAID			Compatible	May be classified B or C in early pregnancy, D near term
Nystatin			Compatible	
Odansetron			No data	
Oxacillin		Antibiotic	Compatible	
Oxycodone		Narcotic	Compatible	
Paroxetine	Paxil	Antidepressant	Possible long-term neurobehavioral effects of concern	
Penicillin			Compatible	
Pentazocine		Narcotic	No data	
Permethrin	Scabicide,topical		No data	
Pindolol			Compatible	
Ranitidine		Antihistamine	Compatible	
Sertraline	Zoloft	Antidepressant	No data	
Sulbactam			Compatible	
Sulfasalazine			With caution	Classified B in early

				pregnancy, D near term
Terbinafine	Lamisil	Antifungal	Contraindicated	
Terbutaline			Compatible	
Ticarcillin			Compatible	

Category B: Animal studies indicate no fetal risk and no well-controlled human studies have been conducted, or animal studies demonstrate an adverse effect that is not confirmed in controlled human studies.

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Troglitazone	Rezulin	Antidiabetic Agent	No data, contraindicated	
Zolpidem			Compatible	No human data

Category C: Animal studies demonstrate adverse effects on the fetus and no controlled human studies have been conducted, or studies in humans and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus.

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
ACE Inhibitors	Enalapril, Captopril, Lisinopril	Antihypertensive	Compatible	Classified C first trimester, D second and third trimesters
Acetazolamide	Diamox	Diuretic	Compatible	
Acyclovir	Zovirax	Antiviral	Compatible	
Adenosine	Adenocard	Antiarrhythmic	No data	No adequate human studies
Albuterol	Proventil	Antiasthmatic	Compatible	
Alfentanil		Opiate Agonist	Compatible	
Alendronate	Fosamax	Bone Metabolism	No data	No adequate human studies
Allopurinol		Gout,Uricosuric	Compatible	No adequate human studies
Amantadine	Symmetrel	Antiviral	Contraindicated	
Amikacin	Amikin	Antibiotic	Compatible	No adequate human studies
Aminocaproic acid	Amicar	Hemostatic	No data	No adequate human studies
Aminoglycosides		Antibiotic	Compatible	
Aminopyhlline	Aminop	Antiasthmatic	Compatible	
Amiodarone	Cordarone	Antiarrhythmic	Contraindicated	No adequate human studies

Amlodipine	Norvasc	Antihypertensive	No data	No adequate human studies
Amoxapine	Asendin	Antidepressant	Compatibility unknown	
Amphetamine		Respiratory and Cerebral Stimulant	Contraindicated	Nonteratogenic when used under medical supervision
Aspirin		Nonsteroidal Antiinflammatory Agent	With caution	Classified C in low dose (<150 mg/day), D in standard doses
Atenolol		Antihypertensive	Compatible	
Atropine		Antimuscarinic	Compatible	

Category C: Animal studies demonstrate adverse effects on the fetus and no controlled human studies have been conducted, or studies in humans and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus.

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Baclofen		Skeletal Muscle Relaxant	Compatible	
Beclomethasone	Vancenase, Vanceril	Corticosteroid	No data	
Benzepril	Lotensin	Antihypertensive Agent	Compatible	Classified C first trimester, D second and third trimesters
Benztropine	Cogentin	Anti-Parkinsonnian Agent	No data	Possible association with cardiovascular defects
Betamethasone	Celestone	Corticosteroid	No data	
Betaxolol	Betoptic	Treatment of Glaucoma	With caution	
Bethanechol		Cholinergic Agent	Contraindicated	
Bismuth subsalicylate	Pepto Bismol	Antidiarrheal Agent	With caution	
Bromocriptine	Parlodel,Ergoset	Treatment of Hyper-prolactinemia	Contraindicated	
Brompheniramine		Antihistamine	Compatible	

Butalbital		Intermediate-Acting Barbituate	No data	
Butoconazole	Femstat, Mycelex	Antifungal,Topical	No data	
Butorphanol	Stadol	Analgesic	Compatible	
Calcitonin	Miacalcin	Calcium Metabolism	No data	
Calcium Channel Blockers			Compatible	
Carbamazepine	Tegretal,Carbatrol	Anticonvulsant	Compatible	
Carisoprodol	Soma	Skeletal Muscle Relaxant	Avoid breastfeeding	
Celecoxib	Celebrex	Nonsteroidal Antiinflammatory Agent	Compatibility unknown	
Chloramphenicol	Chloromycetin	Antibiotic	Contraindicated	
Chloroquine	Aralen	Antimalarial Agent	Compatible	
Chlorpromazine	Thorazine	Tranquilizer	With caution	
Chlorpropamide	Diabinese	Antidiabetic Agent	Contraindicated	
Cholestyramine	Prevalite	Antilipemic Agent	No data	
Ciprofloxacin	Cipro	Antiinfective	Contraindicated, discontinue feeding for 48 hours after last dose	

Category C: Animal studies demonstrate adverse effects on the fetus and no controlled human studies have been conducted, or studies in humans and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus.

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Cisapride	Propulsid	Treatment of Gastroesophageal Reflux Disease	Compatible	
Citalopram	Celexa	SSRI	Avoid breastfeeding	No adequate human studies
Clarithromycin	Biaxin	Antiinfective	No data	
Clemastine		Antihistamine	With caution	
Clofibrate	Atromid-S	Anilipemic Agent	Contraindicated	
Clonidine	Catapres	Antihypertensive	Contraindicated	
Cocaine			Contraindicated	Classified X as an illicit drug
Codeine	Opiate Agonist		Compatible	

Crotamiton		Treatment of Scabies	No data	
Cyclosporine	Neoral, Sandimmune	Antineoplastic Agent	Contraindicated	
Desipramine			Compatible	
Dexamethasone			No data	
Dexfenfluramine			Not recommended	
Diazoxide			Contraindicated	
Digoxin	Lanoxin	Antiarrhythmic	Compatible	
Diltiazem	Cardizem	Calcium channel blocker	Compatible	
Diphenhydramine		Antihistamine	No data	
Dipyridamole			Compatible	
Disopyramide			Compatible	
Docusate Salts			With caution	
Donepezil	Aricept	Acetyl-cholinesterase inhibitor	Compatibility unknown	
Doxazosin	Cardura	Alpha adrenergic receptor inhibitor	Compatibility unknown	
Doxepin			Contraindicated	
Droperidol			No data	
Enalapril	Vasotec	Antihypertensive	Compatible	Classified C first trimester, D second and third trimesters
Ephedrine			Compatible	
Epoetin Alfa			No data	
Ethosuximide			Compatible	
Felodipine	Plendil	Calcium channel blocker	Compatibility unknown	
Fexofenadine	Allegra	Antihistamine	Compatibility unknown	
Fluconazole			Contraindicated	
Fluphenazine			No data	

Category C: Animal studies demonstrate adverse effects on the fetus and no controlled human studies have been conducted, or studies in humans and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus.

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Fluticasone	Flovent	Corticosteroid	Compatibility unknown	No adequate human studies

Fosinopril		Antihypertensive	Not compatible according to drug manufacturer	Classified C first trimester, D second and third trimesters
Furosemide	Lasix	Diuretic	With caution	
Gabapentin	Neurontin	Anticonvulsant	Compatibility unknown	No adequate human studies
Gemfibrozil	Lopid	Hyperlipidemia	No data	
Gentamicin	Garamycin	Antibiotic	Compatible	
Glimepiride	Amaryl	Blood Glucose Regulator	No data	
Glipizide	Glucotrol	Blood Glucose Regulator	Contraindicated	
Glyburide	Diabeta,Micro nase	Blood Glucose Regulator	Contraindicated	
Gold salts			With caution	
Guaifenesine	Robitussin	Expectorant	No data	
Hydralazine		Antihypertensive	Compatible	
Hydroxyzine	Atarax,Vistaril	Anxiolytic-Sedative and Hypnotic	No data	
Hydro-zychloroquine	Plaquenil	Antimalarial Agent	Compatible	
Irbesartan	Avapro	Antihypertensive	No data	Classified C first trimester, D second and third trimesters
Isoniazid		Antituberculosis Agent	Compatible if also on pyridoxine	
Isoproterenol		Sypathomimetic Agent	Compatible	
Ketorolac	Toradol	Nonsteroidal Antiinflammatory Agent	Contraindicated	
Labetolol		Antihypertensive	Compatible	
Latanoprost	Xalatan Opthalmic Solution	Treatment of Glaucoma	Compatibility unknown	
Levodopa			Contraindicated	
Levofloxacin	Levaquin	Antiinfective	Compatibility unknown	
Lisinopril	Prinivil,Zestril	Antihypertensive	No data	Classified C first trimester, D second and third trimesters

Category C: Animal studies demonstrate adverse effects on the fetus and no controlled human studies have been conducted, or studies in humans and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus.

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Losartan	Cozaar	Antihypertensive	No data	Classified C first trimester, D second and third trimesters
Mebendazole			Compatibility unknown	Manufacturer recommends against use in pregnancy
Mefenamic Acid	Ponstel	Nonsteroidal Antiinflammatory	Compatible	
Mepindolol			Compatible	
Methyldopa			Compatible	
Methylphenidate	Concerta,Ritalin	Respiratory and Cerebral Stimulant	No data	
Metoprolol			Compatible	
Mineral Oil			With caution	
Minoxidil		Antihypertensive Agent	Compatible	
Mometasone	Elocon,Nasonex	Antiinflammatory Agent, Topical	No data	
Nabumetone	Relafen	Nonsteroidal Antiinflammatory Agent	Not recommended according to drug manufacturer	
Nalidixic Acid	NegGram	Antiinfective	Compatible	
Nefazodone	Serzone	Antidepressant	No data	
Nifedipine	Adalat,Procardia	Antihypertensive Agent	Compatible	
Nitrogylcerine	Nitrolingual,Nitrol	Vasodilating Agent	No data	
NSAID			Compatible	Classified B or C in early pregnancy, D near term
Ofloxacin	Floxin	Antiinfective	Contraindicated	

Olanzapine	Zyprexa		Not recommended according to drug manufacturer	
Olsalazine			With caution	
Omeprazole	Prisolec	Control of stomach acid	Not recommended	
Oxaprozin	Daypro	Nonsteroidal Antiinflammatory	No data	
Oxazepam			Minimal dose	
Paromycin			Compatible	
Phenothiazine			With caution	
Phenyl-propanolamine		Decongestant	Compatible	

Category C: Animal studies demonstrate adverse effects on the fetus and no controlled human studies have been conducted, or studies in humans and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus.

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Piroxicam		Nonsteroidal Antiinflammatory	Compatible	
Podofilox		Treatment of Genital Warts	No data	
Podophyllin		Treatment of Genital Warts	No data	
Potassium Chloride	K-Dur		Compatible	
Procainamide			Compatible	
Prochloperazine			Compatible	
Promethazine			With caution	
Propanolol			Compatible	
Propoxyphene			Compatible	
Pseudoephedrine			Compatible	
Pyrantel Pamoate			No data	
Pyridostigmine			Compatible	
Pyrimethamine			Compatible	
Quinapril	Accupril	Antihypertensive	Compatibility unknown	Classified C first trimester, D second and third trimesters

Quinidine			Compatible	
Ramipril	Altace	Antihypertensive	Not recommended by drug manufacturer	Classified C first trimester, D second and third trimesters
Repaglinide		Antidiabetic	Contraindicated	
Reserpine		Antihypertensive Agent	Compatible	
Rifampin		Antituberculosis Agent	Compatible	
Risperidone	Risperdal	Antipsychotic	No data	
Rofecoxib	Vioxx	Nonsteroidal Antiinflammatory	No data	
Salmeterol	Serevent	Bronchodilator	No data	
Sumatriptan			Compatible	
Spironolactone			Compatible	
Sulfapyridine/ Sulfisoxazole			Contraindicated	
Temazepam			Compatible	
Terfenadine			No data	
Theophylline			Compatible	
Thioridazine			Compatible	
Timolol			Compatible	
Tinidazole			Contraindicated	
Tolbutamide			Compatible	
Tolmetin			Compatible	

Category C: Animal studies demonstrate adverse effects on the fetus and no controlled human studies have been conducted, or studies in humans and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus.

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Tramadol			Not recommended	No adequate human studies
Triamcinolone Acetonide	Azmacort	Corticosteroid	No data	
Triamterene	Dyazide	Antihypertensive	No data, contraindicated	
Trifluoperazine			Compatible	
Tri-methobenzamide			Compatible	
Trimethoprim/ Sulfamethaxazole			Compatible	

Triprolidine			Compatible	
Vaccine, Cholera			Compatible	
Vaccine, Haemophilus B			Compatible	
Vaccine, Hepatitis A			Compatible	
Vaccine, Hepatitis B			Compatible	
Vaccine, Influenza			Compatible	
Vaccine, Menigococcus			No data	
Vaccine, Plague			No data	
Vaccine, Pneumococcal			Compatible	
Vaccine, Poliovirus Inactivated			No data	
Vaccine, Poliovirus Live			No data	
Vaccine, Rabies			No data	
Vaccine, Rubella	Meruvax		With caution	Avoid pregnancy for three months following vaccination
Vaccine, Typhoid			No data	
Vancomycin			No data	
Venlafazine	Effexor	Antidepressant	Contraindicated	
Verapamil			Compatible	
Vitamin B12			Compatible	
Zidovudine			Contraindicated in HIV infection	

Category D: Positive evidence of human fetal risk exists, but the benefits of use during pregnancy may be acceptable despite risk.

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
ACE Inhibitors	Enalapril, CataoprilLisinopril	Antihypertensive	Compatible	Classified D second and third trimesters, C first trimester

Alprazolam	Xanax	Antianxiety	Contraindicated	
Amitroptyline	Elavil	Antidepressant	Compatible, effect on infant unknown	
Aspirin		Nonsteroidal Antiinflammatory Agent	With caution	Classified D in standard dose, C in low dose
Atenolol	Tenormin	Antihypertensive	Compatible	Intrauterine growth retardation if started in second trimester
Azathioprine	Imuran	Antineoplastic	No data	
Barbituates			With caution	
Benazepril	Lotensin	Antihypertensive	Compatible	Classified D second and third trimester, C in first trimester
Bleomycin		Antineoplastic	No data	
Bumetanide	Bumex	Diuretic	Contraindicated	
Carbimazole		Antithyroid Agent	With caution	
Captopril		Antihypertensive	Compatible	Avoid during pregnacy, associated with intrauterine growth retardation
Chlordiazepoxide	Librium	Sedative	Contraindicated	
Chloropropamide		Antidiabetic	With caution	
Chlorothiazide	Diuril	Diuretic	Compatible	
Cisplatin		Antineoplastic	With caution	
Clonazepam	Klonopin	Anticonvulsant	Contraindicated	
Colchicine		Treatment of gout	Contraindicated	
Cyclophosphamide	Cytoxan	Antineoplastic Agent	Contraindicated	
Dextro-amphetamine			Contraindicated	
Diazepam			With caution	
Dicumarol			Compatible	
Divalproex	Depakote	Anticonvulsant	Compatible	
Doxorubicin			Contraindicated	

Doxycycline			Compatible	
Enalapril	Vasotec	Antihypertensive	Compatible	Classified D second and third trimesters, C first trimester

Category D: Positive evidence of human fetal risk exists, but the benefits of use during pregnancy may be acceptable despite risk.

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Fosinopril		Antihypertensive	Not compatible according to drug manufacturer	Classified D second and third trimesters, C first trimester
Hydro-chlorothiazide		Diuretic, Antihypertensive	No data	
Hydrocodone	Vicodin	Narcotic Analgesic	No data	Also classified B
Hydromorphone	Dilaudid	Narcotic Analgesic	Compatible	Also classified B
Imipramine	Tofranil	Antidepressant	With caution	
Indomethacin	Indocin	Nonsteroidal Antiinflammatory Agent	Compatible	Also classified B
Irbesartan	Avapro	Antihypertensive	No data	Classified D second and third trimesters, C first trimester
Kanamycin			Compatible	
Lisinopril	Prinivil,Zestril	Antihypertensive	No data	Classified D second and third trimesters, C first trimester
Lithium			Contraindicated	8% risk of serious cardiovascular anomaly, 2.7% risk of Ebstein anomaly
Lorazepam			With caution	
Losartan	Cozaar	Antihypertensive	No data	Classified D second and third trimesters, C first trimester

Medroxy-progesterone			Compatible	
Meperidine			Minimal dose	Also classified B
Meprobamate			Contraindicated	
Mercaptopurine		Immino-suppressant	No data	
Methadone		Narcotic	With caution	Also classified B
Methotrexate		Immuno-suppressant	No data	
Methimazole			With caution	
Methotrexate	Methotrex, Rheumatrex	Antineoplastic Agent	Contraindicated	
Morphine		Narcotic	Compatible, inhibits milk	Also classified B
Nortriptyline			No data	

Category D: Positive evidence of human fetal risk exists, but the benefits of use during pregnancy may be acceptable despite risk.

Generic Name	**Brand Name**	**Drug Type**	**Breastfeeding**	**Additional Notes**
NSAID			Compatible	Classified D near term, B or C in early pregnancy depending on compound
Penicillamine			Contraindicated	
Phenobarbital			With caution	
Phenytoin		Anticonvulsant	Compatible	
Potassium Iodide			Contraindicated	
Primidone			With caution	
Progesterone			Compatible	
Propylthiouracil			With caution	
Quinapril	Accupril	Antihypertensive	Compatibility unknown	Classified D second and third trimesters, C first trimester
Ramipril	Altace	Antihypertensive	Contraindicated according to	Classified D second and

			drug manufacturer	third trimesters, C first trimester
Secobarbital			Compatible	
Sulfasalazine			With caution	Classified D near term due to risk for kernicterus, B in early pregnancy
Tetracyclines			Compatible	
Tobramycin			Compatible	
Vaccine, Yellow Fever			No data	Avoid in first trimester
Valproic Acid			Compatible	Incidence of spina bifida after first trimester exposure approximately 1%
Vitamin D			Compatible	Also classified A
Warfarin	Coumadin	Anticoagulant	Compatible	

Category X: Human or animal studies indicate fetal abnormalities due to drug use during pregnancy. The risk to the fetus outweighs any possible benefit.

Generic Name		Drug Type	Breastfeeding	Additional Notes
Aminopterin			No data	Multiple gross anomalies, fetal death, postnatal growth retardation, craniofacial abnormalities
Atorvastatin	Lipitor	Antilipemic	No data	
Clomiphene	Clomid,Serophene	Nonsteroidal Ovulatory Stimulant	No data	
Cocaine			Contraindicated	Classified X as an illicit drug, otherwise C
Contraceptives, oral			Compatible	
Dienestrol			No data	Cardiovascular defects
Diethylstilbesterol			No data	
Dihydro-streptomycin			No data	Hearing loss
Disulfiram			No data	Spontaneous abortion, club feet
Ergotamine			Contraindicated	Spontaneous abortion, CNS symptoms, Poland syndrome
Erythromycin Estolate			With caution	
Ethanol			Minimal dose	
Etretinate			No data	
Estrogens			No data	
Fluvastatin	Lescol	Hyperlipidemia	No data	
Gallium-69			Contraindicated, radioactivity in breast milk for two weeks	
Gaseous			No data	Spontaneous

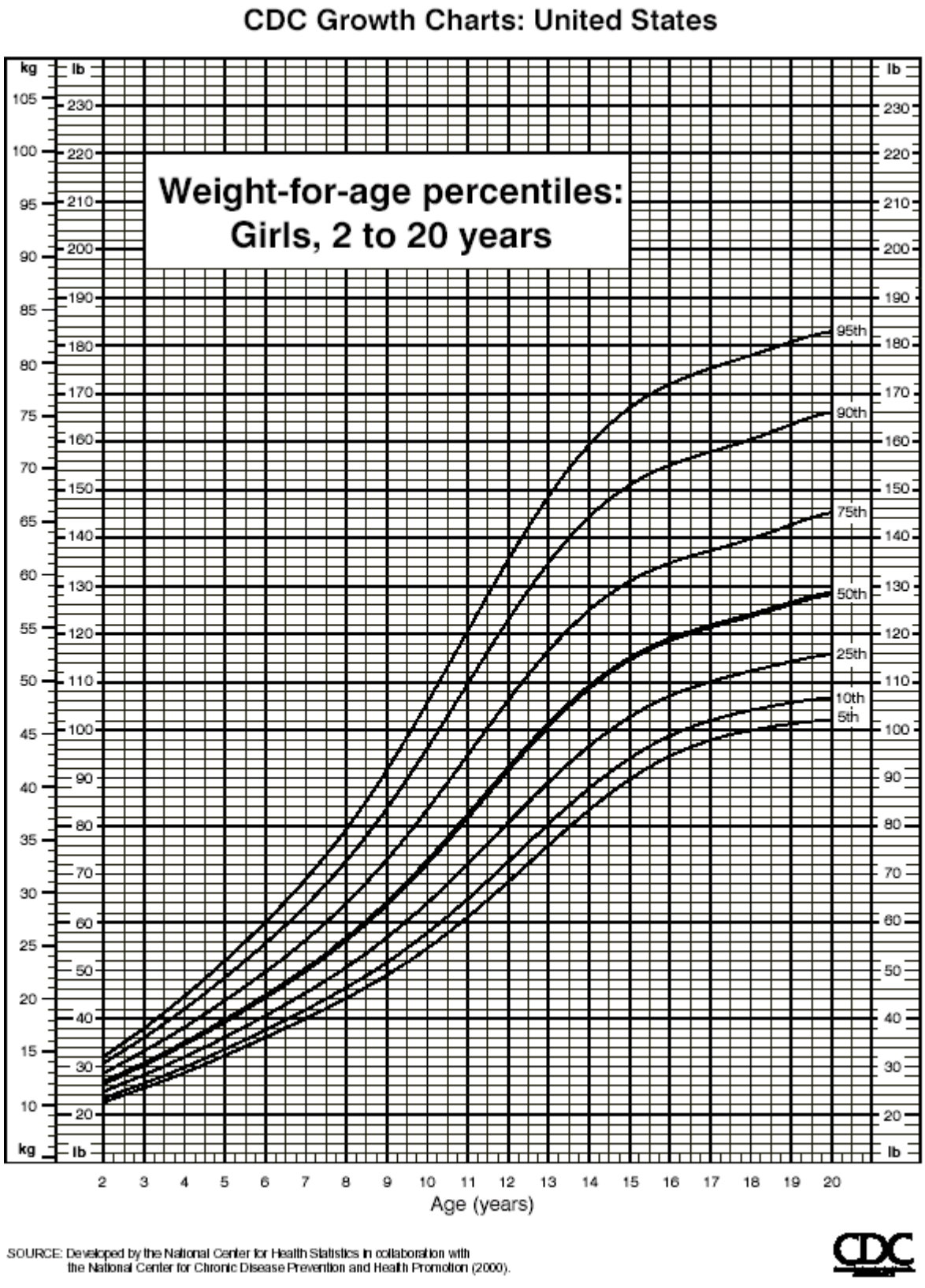
Anesthetics				abortion
Iodine-125			Contraindicated, radioactivity in breast milk for two weeks	
Iodine-131			No data	Cretinism, hypothyroidism
Isotretinoin	Accutane	Skin and Mucus Membrane Agent	Contraindicated	16% spontaneous abortion, 19% major malformations
Methyltestosterone			No data	
Misoprostol			Contraindicated	

Category X: Human or animal studies indicate fetal abnormalities due to drug use during pregnancy. The risk to the fetus outweighs any possible benefit.

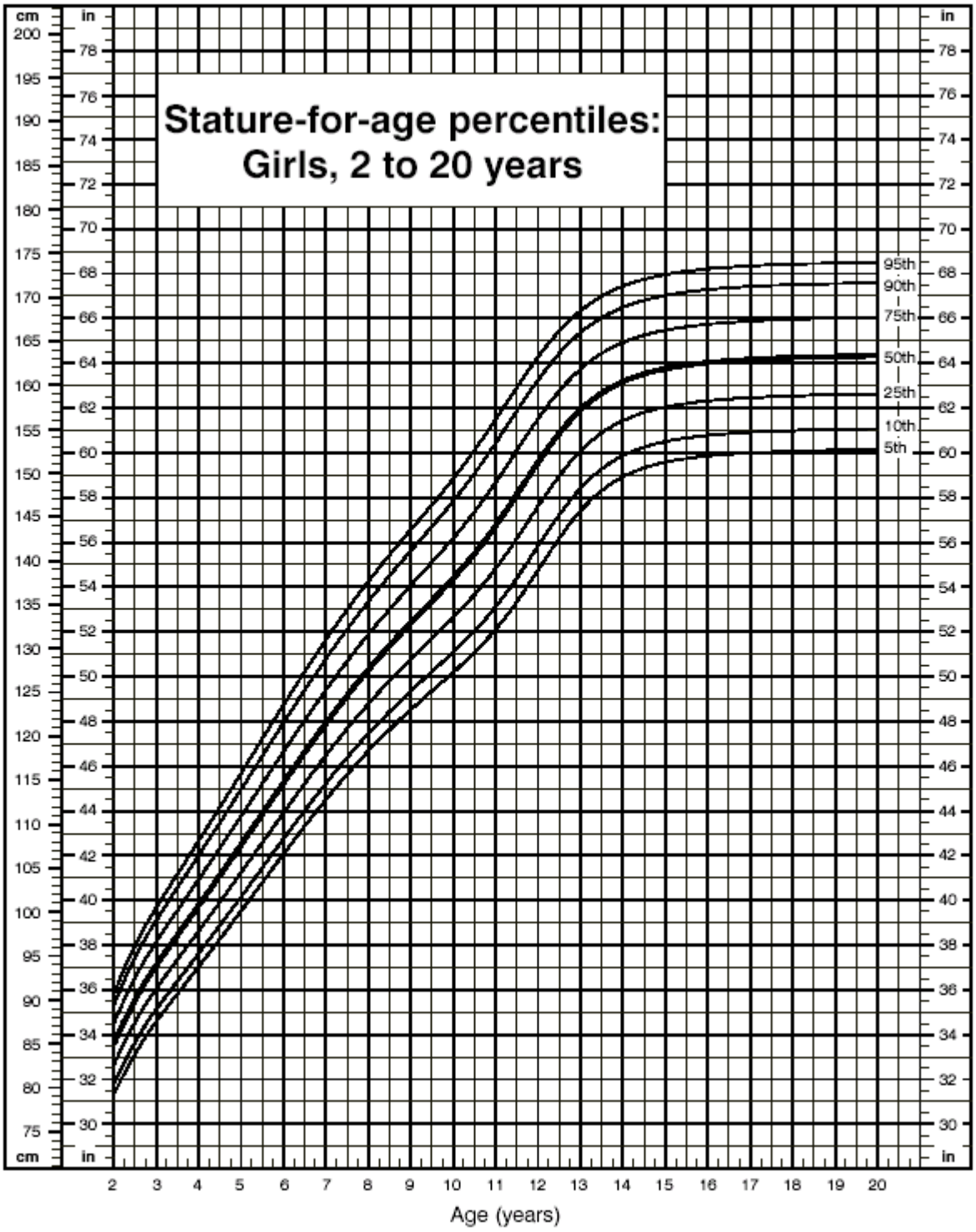
Generic Name		Drug Type	Breastfeeding	Additional Notes
Nicotine			Contraindicated, decreased milk production	
Premarin			Contraindicated	
Progestins			No data	
Quinine			No data	Mental retardation, fetal death
Raloxifene	Evista	Selective Estrogen Receptor Modulator	Contraindicated	
Simvastatin	Zocor	Antipemic Agent	No data	
Technitium-99m			Contraindicated, radioactivity in breast milk for three days	
Thalidomide			No data	Limb defects, anomalies of cardiac, renal, and gastroinstestinal systems
Trimethadione			No data	
Vaccine, Measles			No data	Avoid pregnancy for three months following

				vaccination
Vaccine, Mumps			No data	Avoid pregnancy for three months following vaccination
Vaccine, TC-83	Venezuelan Equine Encephalitis		No data	Avoid pregnancy for three months following vaccination
Vitamin A			Compatible	Classified X in high doses, otherwise A

Appendix AG: Height and Weight Charts

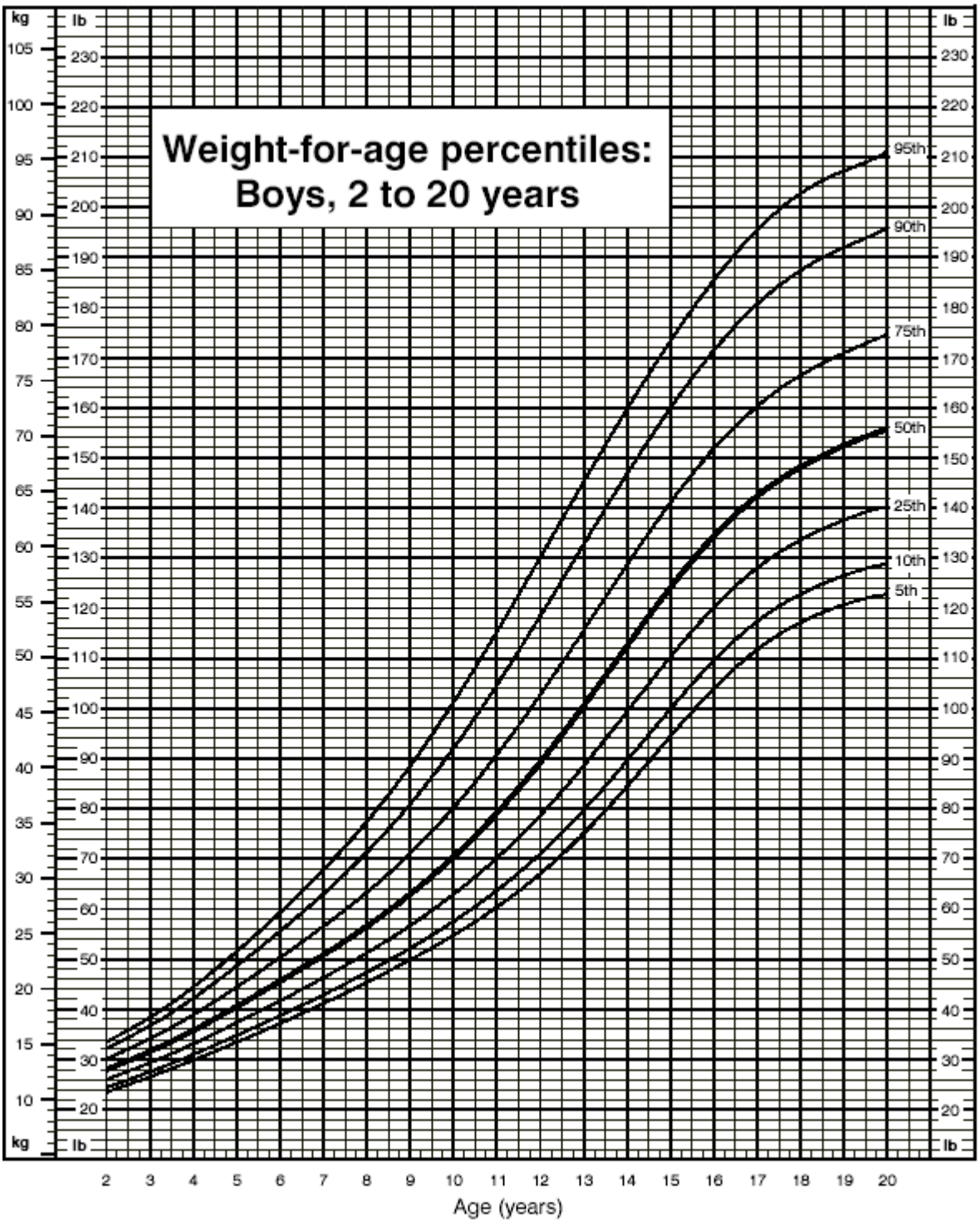


CDC Growth Charts: United States



SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).

CDC Growth Charts: United States



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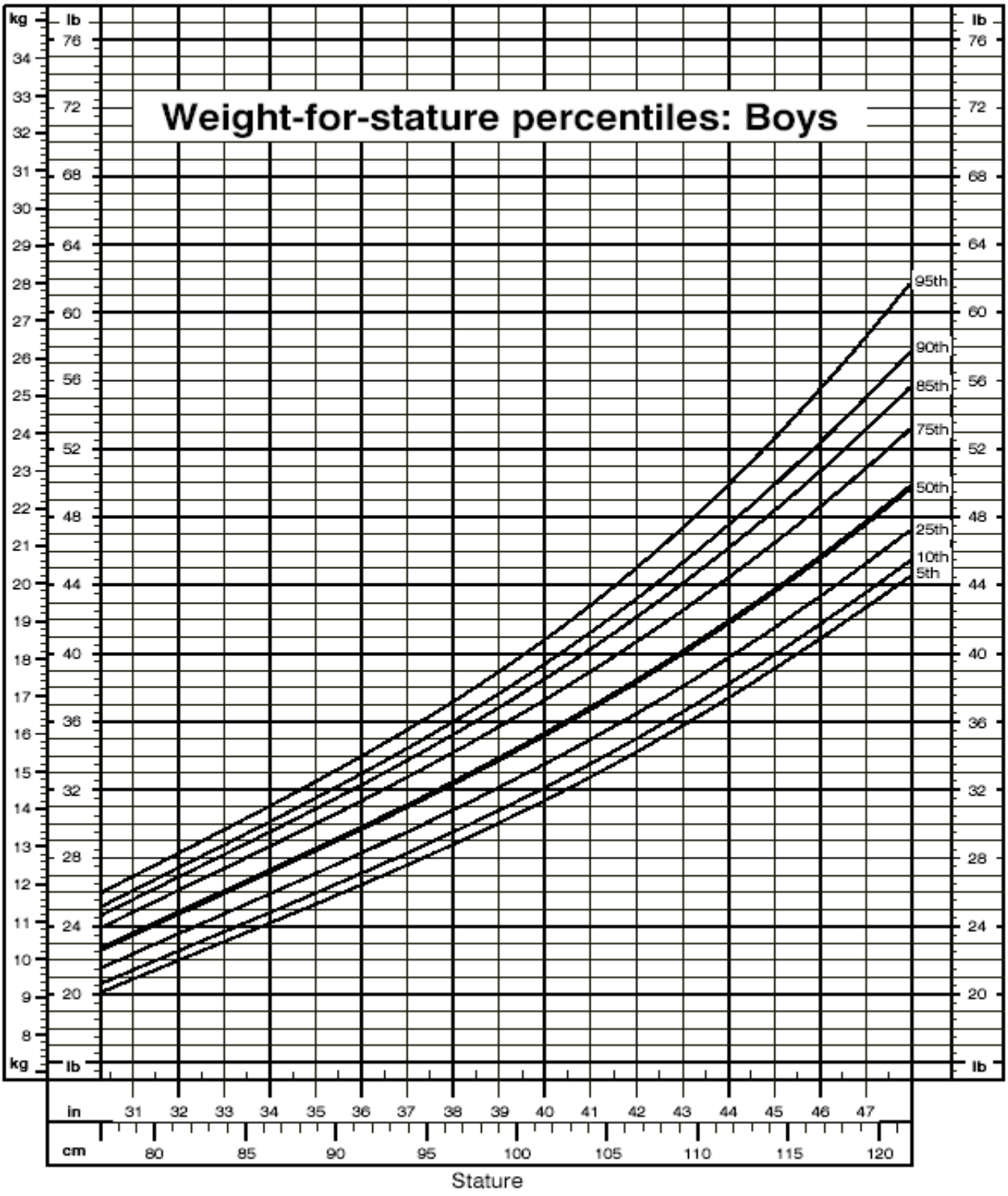
CDC Growth Charts: United States



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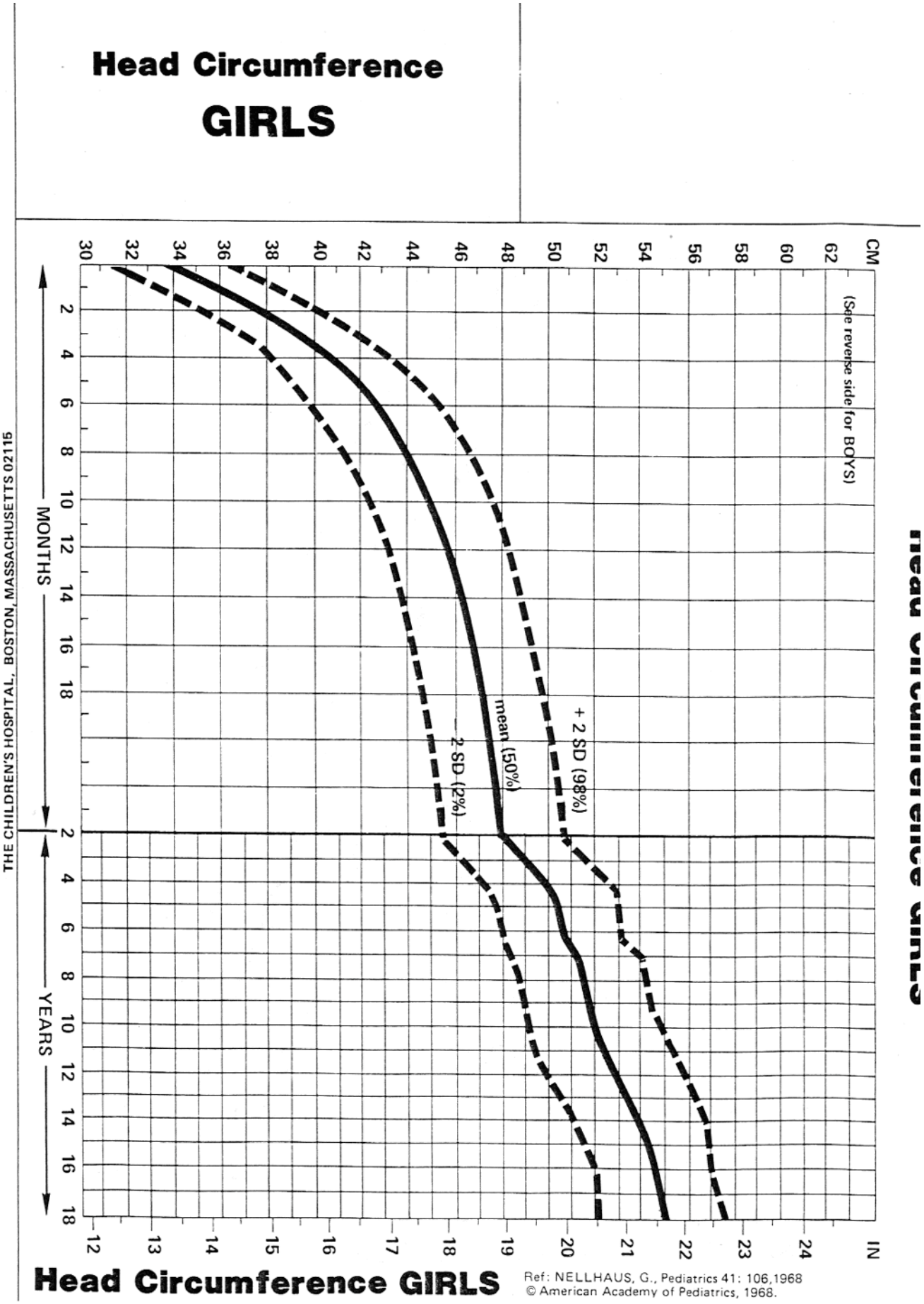
Head Circumference
GIRLS
CM
IN
(See reverse side for BOYS)
+ 2 SD (98%)
mean (50%)
– 2 SD (2%)
MONTHS
YEARS
THE CHILDREN'S HOSPITAL, BOSTON, MASSACHUSETTS 02115
Head Circumference GIRLS
Ref: NELLHAUS, G., Pediatrics 41: 106,1968
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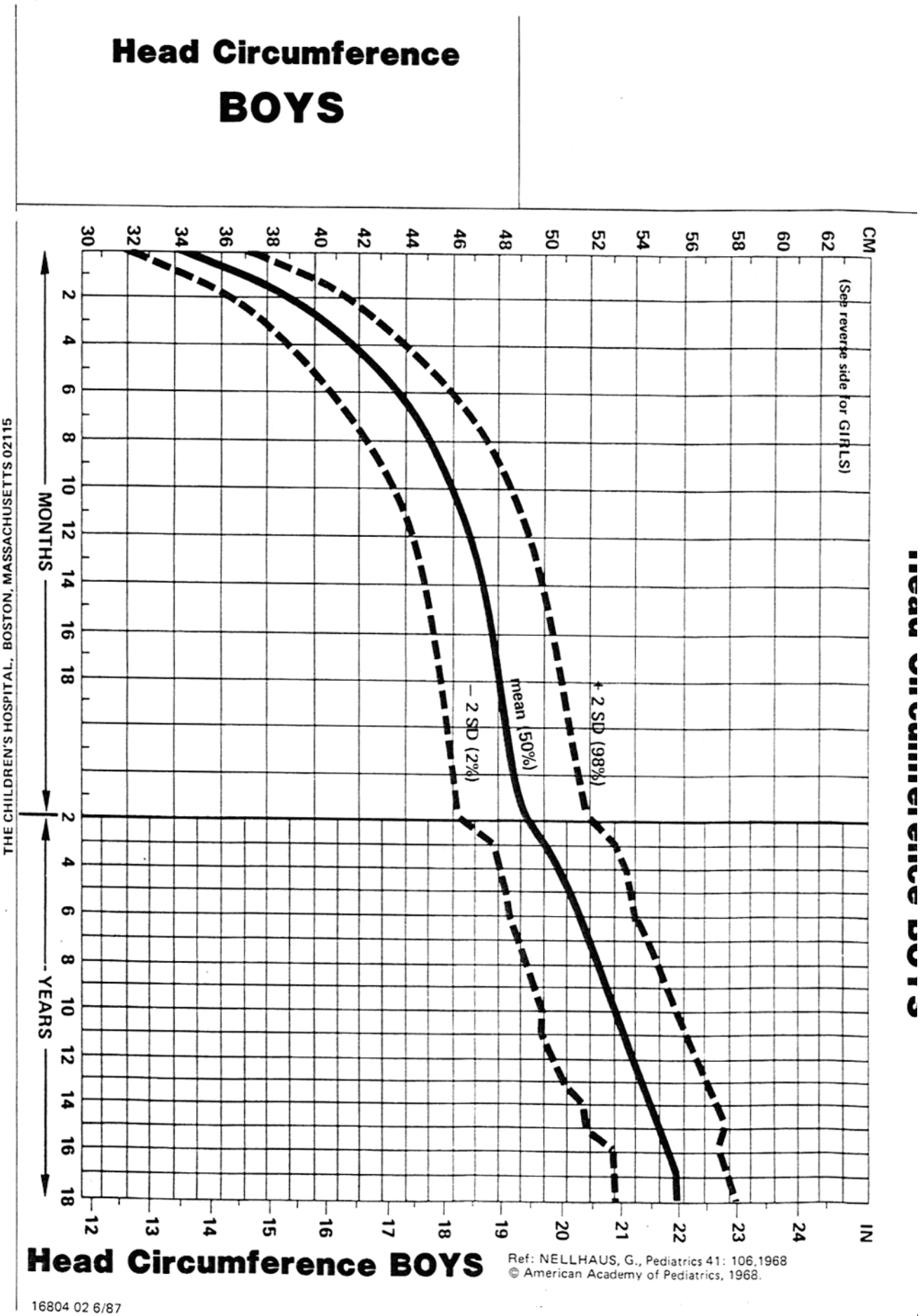
Head Circumference
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